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HOUSE OF REPRESENTATIVES

REPORT
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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1985

JULY 18, 1986.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. DE LA GARZA, from the Committee on Agriculture, submitted the following

REPORT

together with

SUPPLEMENTAL AND DISSENTING VIEWS

[To accompany H.R. 2482]

[Including Congressional Budget Office cost estimate]

The Committee on Agriculture, to whom was referred the bill (H.R. 2482) to amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The Committee amendment strikes out all after the enacting clause and inserts a new text which appears in the appendix to this report.

EXPLANATION OF MAJOR PROVISIONS

SUMMARY

H.R. 2482, as reported by the Committee, will extend the authorization for appropriations for the pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act for 5 years.

It also will substantially amend the Act to improve the pesticide approval process, strengthen provisions that protect the public, make health data available on pesticides, ensure that farmers and other users of pesticides are treated fairly under the pesticide pro-

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gram, and provide an efficient and equitable regulatory program for producers and distributors of pesticides.

The major provisions of the bill include—

—Provisions for public access to pesticide health and safety data.

—New requirements for conditional pesticide registration.

—A new reregistration program to ensure that pesticides with older registrations are reexamined and found to be safe.

—An expanded program for regulation of inert ingredients in pesticides.

—Provisions to enable State agencies to obtain pesticide data from EPA.

—Improvements to the public interim administrative review process (used to review currently registered pesticides for health and safety risks), and the procedures to be followed if a pesticide registration is to be cancelled or denied.

—Provisions for requiring changes in pesticide labels under expedited procedures.

—Sanctions for submission of false health or safety data on a pesticide, and procedures to ensure replacement of invalid data.

—Requirements for withdrawal of tolerances for pesticide residues on raw agricultural commodities if the pesticide registration is suspended or cancelled.

—Updating of provisions relating to recordkeeping and inspections under the Act.

—Warning and information requirements for exported pesticides.

—Improved procedures for training and certifying applicators of pesticides, including refresher training.

—Requirements for recordkeeping by pesticide dealers and applicators, and access to certain records for employees and customers.

—Required cooperation or cost-sharing in the development of health and safety data on currently registered major agricultural pesticides.

—Revisions of the rules under which the compensation must be paid when an applicant for registration of a pesticide uses another person's data in the pesticide registration process.

—A requirement for the establishment of criteria under which State pesticide registrations for special local needs could be disapproved.

—Clarification of the "use inconsistent" definition.

—Provisions to reduce burdensome requests for information under the Act.

—Strengthening of the enforcement and penalty provisions of the Act.

—New procedures for judicial review of the regulation promulgated under the Act, with special provisions for agricultural producers.

—Coordination of action by EPA and the Department of Labor (under OSHA) with respect to pesticide worker safety, and requirements for training and worker protection regulations under the Act.

—A requirement that the Administrator use authorities under the Act to protect drinking water and groundwater against pesticide contamination.
—Establishment of liability rules to protect farmers who use pesticides correctly.

Following are brief descriptions of the major provisions of the bill:

Detailed Explanation

Preregistration access to data: The bill provides for public access to health and safety data submitted to support an application for the registration of a pesticide containing a new active ingredient, or to authorize the initial food use of a pesticide active ingredient. Public access would only be granted for the purpose of allowing public comment on the application. A person seeking access to data supporting an application for registration must affirm that the person is not directly or indirectly, or acting on behalf of someone, in the pesticide business. Criminal penalties would be required for wrongful disclosures of information. (Secs. 101 and 102.)

Conditional registrations: The bill will prohibit conditional registration amendments of a pesticide for additional uses unless the additional use is in the public interest. A conditional amendment to add a use could not be granted if data concerning possible chronic effects have not been submitted, and the registrant has had a reasonable time to submit the data, unless the amendment is to add a minor use. (Sec. 103.)

Reregistration of registered pesticides: The bill will require the Administrator of the Environmental Protection Agency to reregister pesticides with active ingredients contained in pesticides registered before November 1, 1984, with outstanding data requirements. Reregistration would be completed in five phases:

(1) EPA would publish a priority list of the active ingredients contained in pesticides that must be reregistered. Priority would be given to active ingredients that have not already been assigned reregistration requirements, and that are in use on or in food or feed and may result in postharvest residues or residues of potential toxicological concern in potable groundwater, edible fish, or shellfish, have significant outstanding data requirements, or are used where workers exposure is most likely.

(2) Registrants must notify the Administrator whether or not the registrant intends to seek reregistration of a listed pesticide. Registrants must also identify and agree to replace missing and inadequate data for the pesticide.

(3) Registrants must summarize studies previously submitted in support of reregistration, reformat certain data in the studies according to EPA guidelines, and promise to fill outstanding data requirements.

(4) The Administrator must review submissions to determine if all data that are missing or inadequate were identified. Outstanding data requirements for each active ingredient must be published, and four years would be allowed for the submission of required data.

(5) EPA must conduct a thorough examination of all data, and determine if the pesticide is eligible for reregistration. Applicants for reregistration of the pesticide must then supply supplemental product-specific data. The Administrator must make a final decision on reregistration not later than one year after the submissionof all required data.

The bill provides for the payment of reregistration fees based on active ingredients. Collectively, registrants of each pesticide registered for a major use on food or feed must pay an initial fee of $50,000 with the phase two submission. A final fee of $100,000 would be paid under phase three.

Registrants of each pesticide registered for a major use on food or feed for which registration requirements already have been issued, must collectively pay a fee of $100,000 at a time to be determined by the Adminstrator.

Registrants of each pesticide not registered for a major food or feed use must collectively pay a fee determined by the Administrator (but not greater than $150,000 or less than $75,000). If registration requirements already have been issued for the pesticide, the fee could not be greater than $100,000 or less than $50,000.

Fees could be reduced or waived for minor use pesticides, pesticides for which the value or volume of use is small, certain small businesses, and antimicrobial active ingredients for which production levels do not exceed 1,000,000 pounds per year. Fees are to be apportioned, according to domestic market share, among registrants. (Secs. 104 and 105.)

Inert ingredients: The bill will direct the Administrator to establish a priority list of between 50 and 75 inert ingredients. Listed would be (1) inerts that appear to cause a pesticide to trigger a public interim administrative review; (2) inerts for which additional data are reasonably necessary to assess whether they may cause unreasonable adverse effects, that are similar in molecular structure to chemicals known to cause unreasonable adverse effects, and that have significant use in pesticides or to which there is significant exposure from pesticides; and (3) inerts for which additional data are needed to assess whether they may result in unreasonable adverse effects and to which there is significant exposure from pesticides. Within one year, the Administrator must determine if additional data on a listed inert ingredient are needed, and such data must be submitted within four years. Within one year after submission of the data, the Administrator must take appropriate regulatory action.

The bill would require modification of pesticide ingredient statements to show the name of each inert ingredient in a pesticide that the Administrator determines must appear in the statement because of the hazard that may be posed by the use pattern and concentration level of the inert ingredient, and the name of any inert ingredient for which the Administrator has required additional data because it appears to cause a pesticide to trigger a public interim administrative review (Secs. 106 through 109.)

Public right to know: The bill will require that any producer operating a pesticide production establishment to prepare or obtain a fact sheet, summarizing relevant health, safety, and environmental data for each active ingredient manufactured or used at the estab-

lishment. The producer must furnish a copy of the fact sheet to any person on request. Producers must furnish to EPA annual reports that include the name of each ingredient for which a fact sheet is required, the location of the establishment, and a copy of the most current fact sheet. Fact sheets and annual reports must be made available to the public. (Sec. 201.)

Data disclosure to states: The bill will require the Administrator to disclose to a State data or information acquired under the Act if the State provides at least the same protections as the Act with respect to the disclosure and use of the data or information, and State law allows the data submitter to recover just compensation for losses that result from wrongful disclosure, as provided by the Act.

Authorizes appropriations for an EPA committee to develop an efficient system for the dissemination and use of data submitted to the Administrator under the Act. (Sec. 202.)

Public interim administrative review: The bill provides that a public interim administrative review initiated after January 1, 1987, on whether the use of a currently-registered pesticide or category of pesticides poses unreasonable adverse effects to the environment must be conducted as follows:

(1) The Administrator must publish criteria for initiating a review. The criteria must be based on levels of risk and could include consideration of currently available exposure data. Absence of exposure data would not delay initiation of a review. The Administrator could decline to initiate a review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

(2) As under current law, the Administrator could not initiate a review to develop a risk-benefit evaluation of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of the pesticide unless the review is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to the environment.

(3) On receipt of information about a pesticide demonstrating that the criteria for initiating a review have been met, the Administrator must notify all registrants of the pesticide and provide information and an explanation.

(4) If the Administrator intends to initiate a review of a pesticide registered for agricultural uses, the Administrator must notify the Secretary of Agriculture.

(5) Any review must be conducted in accordance with published regulations. The regulations must provide that a review will include a notice of initiation of the review; a notice of preliminary determination; and a notice of final determination. Public comment must be provided for in the notice of initiation and the notice of preliminary determination.

(6) The notice of initiation or the notice of preliminary determination must state the basis for the review or determination and request any additional data needed, and a bibliography of all scientific data, studies, and expert analysis concerning those risks or benefits of the pesticide that are under review. A person must submit comments within 90 days and disclose all scientific data, studies,

and expert analyses in the person's possession about the pesticide that were not included in the bibliography.

(7) Within 18 months after initiating a review, the Administrator must decide what further regulatory action (if any) to take. (Sec. 301.)

Public hearings resulting from a public interim administrative review: The bill will establish the following special rules to govern hearings that result from the final decision of the Administrator in a public interim administrative review initiated after January 1, 1987:

(1) Any person who is adversely affected by a decision of the Administrator, including a person without an economic interest in the pesticide, could request a hearing within 30 days of the decision. A person could request a hearing, or intervene in a hearing, only if that person submitted comments during the review.

(2) At the request of a party to the hearing, the administrative law judge (ALJ) could receive into evidence portions of the review record and other evidence if the party demonstrates the evidence is relevant and material to the disputed issues, is not unduly repetitious, and a competent witness if made available to be cross-examined about the evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the review would not be admissible at the hearing. The right of parties to confront and cross-examine witnesses would be preserved on material issues of adjudicative facts.

(3) Not later than 120 days after the ALJ is appointed, prehearing matters must be completed and the hearing begun. The ALJ could establish a schedule for prehearing matters, and must ensure that the hearing schedule is met.

(4) Any challenge to the notice of intent to cancel or change classification stemming from the review, or to any request for a hearing or motion to intervene, must be filed with the ALJ before the evidentiary phase of the hearing. Not later than 30 days before the hearing begins, the parties must exchange witness lists, a summary of testimony, and a list of all documents and exhibits to be introduced at the hearing. The presentation of evidence must be completed within 60 days after commencement of the hearing. The person who requested a hearing on an issue will have the burden of going forward to present an affirmative case and have the burden of proof on that issue.

(5) A hearing must be completed and the Administrator must make a final decision within 300 days of the issuance of the final review notice that gave rise to the hearing. (Sec. 302.)

Cancellation and change in classification on labels: The bill will add a new provision to current law to require that any request for a hearing on cancellation must identify the findings and conclusions of the Administrator that are disputed, and include a complete statement of the reasons and factual basis that support the request for a hearing. Any party may identify findings and conclusions in dispute. Before convening a hearing on the request of a person without an economic interest in the pesticide, the Administrator must determine that the request presents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment.

The bill also will authorize pesticide label changes that could be required by the Adminstrator through informal rulemaking, as follows:

(1) The Administrator could not require label changes that are equivalent to a cancellation of a use, render the product unmarketable, or otherwise have a major economic effect on persons affected by the changes.

(3) Once a regulation is promulgated, the Administrator must notify each registrant or user of the pesticide of the label change required by the regulation. Thirty days must be provided for registrants to apply for amendments to registrations to comply with the regulation.

(4) At a hearing requested by a registrant or user of a pesticide that is subject to the regulation, the scope of the hearing will be limited to whether—

(a) the pesticide complies with the regulation;

(b) the regulation by its terms is applicable to the pesticide; and

(c) because of significant new information it would be unreasonable to require compliance with the regulation.

(5) In an action for review of a label regulation, on request, the court must stay the regulation if the petitioner shows a likelihood of success on the merits, and that implementation of the regulation would cause a risk of substantial harm to the petitioner. The court could not stay the regulation if the Administrator shows that failure to implement the regulation would cause a risk of substantial harm to health or the environment. (Sec. 303.)

Public hearings on cancellation: The bill provides that, as soon as practicable after completion of a hearing on the cancellation of a pesticide registration (but not later than 18 months after the issuance of the cancellation notice that gave rise to the hearing), the Administrator must evaluate the data and reports and take appropriate regulatory action. This time period could be extended by the Administrator under extraordinary circumstances for not more than one year. (Sec. 304.)

Administrative changes: The bill will allow a pesticide registrant any time to request that any of its registrations be cancelled or amended to delete one or more uses. Before acting upon the request, the Administrator would be required to publish a notice of the receipt of the request.

The bill will specify that notices of certain regulatory action under the Act must be published in the Federal Register and sent by certified mail, return receipt requested, to the registrant's or applicant's address of record.

The bill will restate and clarify existing law to require that if, at any time after registration a registrant has additional information regarding unreasonable adverse effects of his pesticide on the environment, the information must be submitted to the Administrator. Information would include factual information and expert opinion regarding risks or benefits.

The bill provides that, if the Administrator issues a notice of the denial of registration, a request for a hearing under the Act must be made within 30 days after receipt of the notification. The Administrator could to issue regulations governing the right to a

hearing on denial with respect to a product containing an ingredient that already has been cancelled under the Act. The regulations could give due weight to the desirability of finality of prior proceedings and the extent the applicant had an opportunity to participate in earlier proceedings. (Sec. 305.)

Cancellation of registration based on false or invalid data: The bill will require the Administrator to immediately issue an order of suspension and a notice of intent to cancel a pesticide registration if the Administrator has determined in the Industrial Biotest validation process that the data submitted in support of the registration were invalid and have not been replaced, or are in the process of being replaced but are not submitted by April 1, 1988, and are material to the registration.

The bill specifies that, if the Administrator determines that invalid data have been submitted in support of a registration, the Administrator could either require the registrant to submit valid replacement data on an expedited schedule, or issue a notice of intent to cancel the registration. If a registrant willfully submits material data known to be false in support of registration, the Administrator must immediately issue a notice of intent to suspend or cancel the registration.

The bill will make a suspension or cancellation based on false or invalid data effective 30 days after receipt by the registrant of a notice of the proposed action unless, during the 30-day period, a request for a hearing is made by a person adversely affected.

The bill will limit the matters for resolution at hearings held with respect to false or invalid data and impose a 75-day time limit on the hearing. (Sec. 306.)

Tolerances for agricultural commodities: The bill will require that when pesticide registrations are cancelled or withdrawn or suspended, the Administrator must withdraw any tolerance for residues of the pesticide, or any exemption from the need for a tolerance. The effective date of withdrawal could be delayed under limited circumstances.

The bill also provides that when a pesticide is reviewed under phase five of reregistration, any tolerance for residues of the pesticide or any exemption from the need for a tolerance must be reassessed and established, amended, or revoked as necessary. (Sec. 307.)

Inspections: The bill will clarify existing law to provide that officers or employees of the United States or of any State, duly designated by the Administrator are authorized to—

(1) conduct inspections at pesticide distribution and sales facilities, other places where pesticide records are located, and pesticide testing facilities;

(2) enter any place where the officer or employee has reason to believe that the Act has been or is being violated by any person other than a private applicator; and

(3) execute warrants authorizing entry for inspection purposes, inspection and copying of records, and seizure of any pesticide or device that is in violation of the Act.

The bill will require the Administrator to coordinate inspections with actions taken under other Federal laws. (Sec. 402.)

Export of pesticides: The bill specifies that a pesticide will be considered misbranded if the pesticide is intended for export and is substantially similar in composition and use pattern to a registered pesticide but the label is not written in an appropriate language or does not contain the same health, safety, and hazard precautions as a registered pesticide, unless the precautions on the label would be in conflict with laws of the importing country.

This bill will restrict the export of a pesticide that is classified for restricted use, cancelled, suspended, or not registered for any use. Export of the pesticide would be allowed if 30 days before the first shipment each year, the exporter (1) provides the notice described below to the person importing the pesticide and the appropriate government regulatory office in the importing country, (2) receives written evidence that the notice was delivered to the appropriate government regulatory office, and (3) submits a copy of the notice in English and evidence of delivery to the Administrator.

The Administrator must promptly transmit through the Secretary of State a notice to the appropriate governmental regulatory office of other countries and to appropriate international agencies whenever a registration, or a cancellation or suspension of a registration, becomes effective or ceases to be effective, or a pesticide is classified for restricted use. An annual notice must also be transmitted.

The Administrator must—

(1) actively participate in international efforts to develop and improve pesticide research and regulatory programs;

(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs;

(3) conduct and publish a survey of all countries that import pesticides from the United States or from which the United States imports agricultural commodities, to ascertain what procedures exist in each country regarding the registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides, and to control residues on foods in order to meet tolerances established under United States law. (Secs. 501 through 505.)

Certification, training, and recordkeeping: The bill will make it a violation of the Act for any person to use any pesticides as a commercial applicator unless the person is a certified commercial applicator, or a registered commercial applicator under the direct supervision of a certified commercial applicator. To be considered to be a certified commercial applicator or a registered commercial applicator a person must meet certain requirements and standards.

The bill provides that a restricted use pesticide must be considered to have been applied by, or under the direct supervision of, a certified private applicator only if it is applied by a person who is either a certified private applicator, or a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator. To be considered to be a certified private applicator or supervised private applicator a person must meet certain minimum requirements and standards.

The bill will impose a requirement that each certified applicator and each registered commercial applicator undergo refresher train-

ing and be recertified or reregistered within a period established by the State agency but not to exceed 5 years.

The bill will require the Administrator in consultation with the Secretary of Agriculture to develop certain training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable law, regulations, and labeling. The bill also will require the Administrator to establish minimum standards of competency, and experience or expertise for trainers and minimum standards for training programs.

A State agency could approve any privately administered training program that it determines meets the requirements established under the Act, or requirements established by the State agency, whichever are more stringent.

Federal and State field personnel responsible for on-site observations and inspections of pesticide use must have training that includes training covering materials specified for the commercial application categories for which they are assigned enforcement responsibility.

The bill also will clarify that, in establishing standards applicable to applicators, the Administrator must establish separate standards for commercial applicators and private applicators. (Sec. 601.)

The bill will require each commercial applicator to maintain records of pesticide applications, including the identity and amount of the pesticides applied and the date and location of the applications, for a period of two years. No regulation could require any private applicator to maintain any records or file any reports or other documents.

Each pesticide dealer would have to maintain a record of each sale or distribution of a pesticide classified for restricted use and pesticides designated because they may cause significant adverse effects on health or the environment. The records must include the identify of the pesticide sold, identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer must maintain the records for three years.

A pesticide dealer or commercial applicator must afford to any employee or former employee access to records required to be kept that directly relate to the employee's employment duties. Customers of the dealer or applicator must also have access to records that directly relate to a purchase or application.

State enforcement agencies, as part of an investigation or enforcement action in response to a formal complaint, must make available a report of the findings of the investigation or action to the complainant. At a minimum, the report must include the records required by this section.

An employer who uses or supervises the use of a pesticide must know or have access to the brand name and common or medical name of the pesticide, and know or have access to the safety, first aid, and antidote information listed on the labeling, and make the

information available, on request, to any employee exposed to a pesticide and to treating medical personnel.

Records obtained under these provisions of the bill that are used for commercial purposes would be a violation of the Act. (Sec. 601.)

Data compensation: The bill provides that each registrant of a pesticide that contains an active ingredient that is only used for application in the production of food, feed, or fiber must agree to develop jointly, or share in the cost of developing, the required additional data. If a pesticide is used for application on food, feed, or fiber *and* for other purposes, the registrants of the pesticide who are subject to a requirement to submit additional data must agree to develop jointly the required additional data if the majority of the registrants so agree.

With respect to the amount of compensation that must be paid when a person wishes to use another person's data to register a pesticide, a special rule will apply if the data were submitted on a registered pesticide the patent term of which is extended under an Act of Congress that authorizes an extension of the term of an unexpired patent (irrespective of the date the pesticide underwent its regulatory review period). The amount of compensation to be paid under arbitration for the use of such data would be a fair share of the cost of producing the data plus an additional amount, not to exceed that share, as determined in the arbitration process.

The bill also provides that, in the case of a pesticide with an expired patent, that the terms and amount of compensation for data could be fixed before an application for registration is filed, by arbitration, if requested by the person seeking to use the data. The arbitration proceeding would be binding on the original data submitter and nonbinding on the prospective applicant until the application is filed. Each party would share equally in the fees and expenses of the arbitrators and pay its own attorney's fees. In any subsequent arbitration under this provision (providing for nonbinding arbitration), the party seeking to use the data would pay the fees and expenses of the arbitration, and the attorney's fees for the original data submitter. (Secs. 701 and 702.)

State registrations: The bill will specify that when a State provides a registration for additional uses of a Federally registered pesticide to meet special local needs, the registration will expire and be of no further effect at the end of the period, if any, provided by the State, or 10 days after the date the Administrator publishes a notice that the State no longer desires the registration to continue in effect.

The Administrator must establish criteria that define the conditions under which a special local needs registration may be disapproved by the Administrator, taking into account geographic patterns of use. (Sec. 801.)

Definitions: The bill will clarify that the term "to use any registered pesticide in a manner inconsistent with its labeling" does not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, unless the labeling specifically prohibits a deviation; or (2) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling. (Sec. 802.)

Information requested: The bill will require the Administrator to catalogue and retrieve data under the Act in a manner to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data. (Sec. 803.)

Scientific advisory panel: The bill will make the scientific advisory panel under the Act permanent and expand the panel from 7 members to 9 members. (Sec. 805.)

Authority for EPA action: The bill provides that the Administrator could act upon complaints of information, if a State does not promptly initiate appropriate investigative action after receiving a referral from the Administrator, or does not initiate appropriate enforcement action within 90 days of receipt of the referral. (Sec. 806.)

Expiration of State primary enforcement responsibility: The bill provides that the primary enforcement responsibility of a State with respect to pesticide use violations will expire on January 1, 1989, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in the Act. (Sec. 807.)

Unlawful acts: The bill provides that it would be unlawful for any person to—

(1) knowingly falsify all or part of any records required to be maintained under the Act;

(2) willfully falsify all or part of any information relating to the testing of any pesticide;

(3) willfully submit data known to be false to the Administrator in support of a registration; or

(4) violate certain regulations issued under the Act. (Sec. 808.)

Penalties and subpenas: The bill provides that—

(1) any registrant, applicant for a registration, or pesticide testing facility that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $25,000 for each offense, and not more that $50,000 for a subsequent violation;

(2) any commercial applicator of restricted use pesticides, or any other person who distributes or sells pesticides or devices, that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $10,000 for each offense, and not more than $20,000 for a subsequent violation;

(3) any private applicator who violates any provision of the Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense, and not more than $2,000 for a subsequent violation. The Administrator could waive the requirement for a warning of citation for a first offense by a private applicator if the violation was intentional or caused significant harm to health or the environment;

(4) any registrant, applicant for a registration, or pesticide testing facility that knowingly violates any provision of the Act must be fined not more than $50,000 or imprisoned for not

more than one year, or both. Any commercial applicator of restricted use pesticides, or any person (not including a registrant, applicant for registration, or pesticide testing facility) who distributes or sells pesticides or devices that knowingly violates any provision of the Act must be fined not more than $25,000 or imprisoned for not more than one year, or both.

The maximum penalty for the knowing violation of the Act by a private applicator would be increased from $1,000 to $2,000, and the possible term of imprisonment from 30 days to 60 days.

The Administrator could issue subpenas compelling the attendance and testimony of witnesses, and production of documents. (Sec. 809.)

Congressional review: The bill will repeal current congressional veto provisions applicable to regulations under the Act. Substitute provisions would be provided for the Administrator, simultaneously with the promulgation of any rule or regulation, to transmit a copy to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation would not become effective until 60 calendar days after the rule or regulation is transmitted. (Sec. 810.)

Review of regulations: The bill will allow any person to obtain judicial review of a regulation promulgated by the Administrator, or the refusal by the Administrator of a petition to modify or rescind a regulation, filing a petition for review in the United States court of appeals within 120 days after the date of promulgation or refusal.

A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under the Act would not be subject to judicial review in any suspension, cancellation, or denial proceeding, or in any appeal therefrom, or in certain enforcement proceedings under the Act or in any appeal therefrom, except on request of an agricultural producer who is adversely affected by the action. If a person petitions the Administrator to modify or rescind a regulation in the enforcement proceeding, the application of the regulation must be stayed until the Administrator issues a final decision on the petition. (Sec. 811.)

Delegation and cooperation: The bill will establish that regulatory actions of the Administrator will not preempt the Secretary of Labor from acting under the Occupational Safety and Health Act to prescribe or enforce standards or regulations to the extent that the Administrator and the Secretary of Labor so agree. To ensure the safety and health of workers, the Administrator and the Secretary of Labor must seek to reach agreements and to coordinate the exercise of their statutory authority. (Sec. 812.)

Indemnity report: The bill provides that if the Administrator has taken an action that requires the payment of indemnification, the Administrator must provide a report to the House and Senate Agriculture Committees and the House and Senate Appropriations Committees. (Sec. 813.)

Groundwater authority: The bill will require the Administrator to use the authorities under the Act to provide for the protection of drinking water and groundwater against contamination by pesticides. The Administrator must consult with, and take into account

the views of, the States and the Secretary of Agriculture in exercising this authority. (Sec. 814.)

Worker health and safety: The bill will require the Administrator to promulgate regulations for the protection of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas. The Administrator also must promulgate regulations that provide for the training of employees who mix, load, or apply pesticides. (Sec. 815.)

Liability: The bill will establish that—

(1) an agricultural producer will not be liable in any action brought under any Federal statute for damages caused by pesticide use unless the producer has acted negligently, recklessly, or intentionally. Proof that a pesticide was applied in accordance with label instructions will create a rebuttable presumption that the agricultural producer did not act negligently; and

(2) proof that a pesticide was applied in a manner consistent with the label instructions will create a rebuttable assumption that those provisions of the Act have not been violated. (Sec. 821.)

Evaluation by the Comptroller General: The bill will require the Comptroller General of the United States to conduct an evaluation of the programs and activities authorized by the bill and make a final report to Congress no later than December 31, 1988. (Sec. 822.)

IR-4 program: The bill will require the Secretary of Agriculture to provide support for the interregional project number 4 program (commonly referred to as the "IR-4 program"). (Sec. 823.)

Pesticide risk rating: The bill will require the Administrator to contract with the Board of Agriculture of the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricultural commodities and report the findings of the study to the Administrator and to the House and Senate Agriculture Committees. (Sec. 824.)

Study of nonagricultural pesticides: The bill will require the Administrator to study and report to Congress within one year after the date of the enactment on the pesticide volume, use sites, and target insects for non-agricultural pesticides. (Sec. 825.)

Dioxin study: The bill will require the Administrator to conduct a study under which human breast milk would be tested for residues of isomers of chlorinated dioxins and dibenzofurans. The Administrator must report to Congress the findings from the analysis of the samples not later than 2 years after the date of enactment. (Sec. 826.)

Pesticide drift: The bill will require the Administrator, within 2 years after the date of enactment, to report to the House and Senate Agriculture Committees on the incidence and potential adverse effects on the environment of the drift of pesticides from the site of application at the time of application. (Sec. 827.)

Survey of naturally occurring agents that act as pesticides: The bill will require the Administrator to conduct a survey to determine what research has been, or is being, conducted to establish the extent to which agents that act as pesticides are manufactured by plants. The Administrator must provide a report on the findings of the survey to the House and Senate Agriculture Committees not

later than December 31, 1987, and release the findings to the public. The report must include information on the extent to which the naturally occurring agents have been identified, on the nature of the agents, and on the extent to which the agents have been shown to be toxic, carcinogenic, or mutagenic. (Sec. 828.)

PURPOSE AND NEED

I

Pesticides are chemicals used to control many kinds of pests: insects that attack crops, destroy materials, and carry disease, nematodes, weeds, fungi, others. They have become major components of agricultural production and health protection. Against their benefits, certain hazards must be weighed. Pesticides may be toxic, some persist in the environment, and many pose risks to nontarget organisms.

Federal controls over pesticides began in 1910 with passage of the The Insecticide Act (P.L. 61-152). The Act, administered by the Department of Agriculture, protected the farmer by preventing the manufacture, sale, or transportation of adulterated or misbranded insecticides and fungicides.

During World War II, synthetic organic pesticides were developed for use in the War effort. After the War, the pesticide industry expanded rapidly. In 1947, Congress repealed The Insecticide Act with passage of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The purpose of FIFRA was to protect farmers from ineffective and dangerous pesticides by requiring all pesticides to contain registered labels. The regulatory mechanism to control pesticide use was imposed through the requirement that before a pesticide could be marketed, it must have been granted a "registration" based on what uses were safe and what use restrictions were necessary. The law remained under the jurisdiction of Department of Agriculture.

Over the next two decades, concern grew about hazards to health and the environment from pesticides, but FIFRA remained fundamentally unchanged. However, in 1959 FIFRA was amended (P.L. 86-139) to expand the pesticide products covered to include nemotocides, plant regulators, defoliants, and dessicants. In 1964, following the publication of Rachel Carson's *Silent Spring* and recommendations of the President's Science Advisory Committee report entitled *Use of Pesticides,* FIFRA was amended (P.L. 88-305) to eliminate the "protest registration" that allowed a manufacturer to market a pesticide even if the Department of Agriculture refused to register it. The legislation set up a new method by which manufacturers and the Department could resolve differences concerning reregistration in which the manufacturer could request a hearing or a scientific review committee. The legislation also provided a mechanism for the Secretary of Agriculture to suspend a pesticide registration, thereby immediately halting its sale in interstate commerce. Finally, it permitted the label of a pesticide to bear its registration number (previously a label could not indicate it was registered, so as to avoid any appearance of Department endorsement of the product).

The shortcomings of FIFRA—particularly the inability to control actual usage of pesticides—and the creation of the Environmental Protection Agency (EPA) led in 1972 to a complete revision of FIFRA. The Federal Environmental Pesticide Control Act of 1972 (P.L. 92-516) rewrote FIFRA and transferred authority to implement the pesticide statute from the Department of Agriculture to EPA. The new FIFRA provided for direct controls over pesticide use, for classification of selected pesticides into a restricted category, for registration of manufacturing plants, and for a national monitoring program for pesticide residues. It also added environmental effects to the risks to be weighed in the pesticide registration process.

From the first, EPA had difficulty with its pesticide regulation program and with implementing the 1972 amendments. The agency frequently found itself being criticized by proponents for greater regulation of pesticide use and by those urging less government interference in the pesticide field.

The Federal Pesticide Act of 1978 (P.L. 95-396) culminated 6 years of efforts to overcome implementation obstacles and other problems arising from the 1972 amendments to FIFRA (some amendments had been added in the 1975 reauthorization).

The 1978 Pesticide Act expedited the registration process by providing for registration on the basis of the generic chemical (i.e., active ingredient), allowing conditional registration, developing limited data requirements for minor use pesticides, and providing the developer of a pesticide with a 10-year period of exclusive data use. In addition, States were given primary enforcement responsibilities for the Act. To improve EPA's risk assessment analysis that leads to decisions by the Administrator, the new Act required the agency to obtain guidelines from its Scientific Advisory Panel. The 1978 Act also required the agency, in coordination with the Department of Agriculture, to conduct research into integrated pest management.

II

The purpose of H.R. 2482, as reported by the Committee, is to extend the authorization for appropriations for the pesticide program under the Federal Insecticide, Fungicide, and Rodenticide Act through September 30, 1991; strengthen the protection of public health and the environment; increase public confidence that pesticides are approved and used in a manner consistent with current health and safety requirements; and ensure that pesticide users, including agricultural producers, will have access to the effective and affordable products they need on the farm, in the workplace, and at home. H.R. 2482 also ratifies a number of policies in current practice at the Environmental Protection Agency (EPA).

H.R. 2482 is primarily based on the landmark agreement reached in 1985 proposing substantial revisions to the FIFRA. This accord was reached by the National Agricultural Chemicals Association, representing some 92 pesticide manufacturers, and the Campaign for Pesticide Reform, comprised of 41 environmental, consumer, and labor organizations. The compromise effort now enjoys the support of the American Farm Bureau Federation.

The Committee recognized that the agreement presented an opportunity to break a lengthy stalemate between pesticide manufacturers and users on the one hand, and environmental interests on the other. Although this Committee reported major FIFRA amendments in 1982, which eventually were approved by the House of Representatives, this impasse has thwarted efforts to enact substantive changes in FIFRA.

It is important to note that the spirit of compromise that produced the original agreement carried through to the Committee's work on the legislation. In the course of this process, "wish lists" were abandoned, many old obstacles were removed, and in general, a desire to find the achievable prevailed.

The need for the revisions to FIFRA embodied in H.R 2482 is well documented. In recent years, reviews by this and other Committees of the Congress, the General Accounting Office, the National Academy of Sciences, and others have reported on the exceedingly slow pace of EPA's progress in completing the reregistration of existing pesticides according to current health and safety standards. The reregistration effort has lagged because of inadequate resources, the sheer magnitude of the task, and other reasons. (See "Problems Plague the Environmental Protection Agency's Pesticide Reregistration Activities," Committee on Government Operations, Subcommittee on Environmental and Natural Resources, H.R. Rep. 98-1147, 98th Cong. 2nd Sess. 1982; "EPA Pesticide Regulatory Program Study", House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Agriculture, 97th Cong. 2nd Sess. 1982; "Cancer Causing Chemicals in Food", House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, 95th Cong. 2nd Sess. 1978; "The Environmental Protection Agency and the Regulation of Pesticides", Senate Committee on the Judiciary, Subcommittee on Administrative Practice and Procedure, 94th Cong. 2nd Sess. 1976; General Accounting Office, "Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks", April 1986; General Accounting Office "Delays and Unresovled Issues Plague New Pesticide Protection Programs", 1980; National Academy of Sciences, National Research Council, "Toxicity Testing: Strategies to Determine Needs and Priorities", March 1984; and National Resources Defense Council, "Pesticide Reregistration: An Evaluation of EPA's Progress", April 1986.)

The 1972 FIFRA amendments made pesticide registrations renewable on a five-year basis, and required review of all then-registered products to reassess and ensure their safe use. This general reregistration requirement was originally ordered to be completed by 1975, but the deadline after a brief extension, was dropped altogether in 1978.

As a part of its current reregistration efforts, EPA is developing "registration standards" for each of the approximately 600 pesticide active ingredients that it deems to be commercially important. Development of these reregistration standards entails a review of the data on each active ingredient—a preliminary step—to determine the adequacy of existing data and the need to require registrants to generate studies to replace missing or inadequate data. The Environmental Protection Agency has completed just 127 "in-

terim" reregistration standards and is able to issue only about 25 such interim standards each year.

According to an April, 1986 report by GAO entitled "Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks"—

> Based on current program and resources projection, it appears that reregistration will extend into the 21st century. EPA has been developing about 25 interim registration standards a year and expects to complete these preliminary reassessments around the year 1996. The Agency plans to complete final regulatory standards and tolerances reassessments after receipt and review of all required test data by the year 2005, assuming an increase in resources beginning in fiscal year 1988. The Agency expects that these final standards may cost as much to develop, in both time and resources, as interim standards. As of March 31, 1986, about 17 active ingredients are ready for the development of final registration standards, 12 of which have essentially completed reassessment, according to EPA officials. EPA plans to complete the first final standard in fiscal year 1986. Yet to be done is the reregistration of individual pesticide products following development of final registration standards. Further, EPA will have to maintain final standards to preclude another costly reregistration-type effort sometime in the future.

The halting pace of pesticide reregistration in large part explains why an accelerated reregistration scheme is made the centerpiece of H.R. 2482.

Moreover, concern about the lack of data sufficient to support current pesticide registrations has led to demands for reform in EPA's public interim administrative review and the cancellation process; reinforces the desire by States and their political subdivisions to seek increased control over pesticide use and pesticide residues in food; prompts calls for more stringent protections for workers exposed to pesticides; and increases to efforts to limit pesticide use. Consequently, the polarized public debate that surrounds pesticide use cannot be expected to subside until a successful reregistration program restores confidence in the regulatory system that governs pesticide approval and use.

III

H.R. 2482 proposes several revisions of FIFRA to address many of these concerns. The detailed procedures established for the reregistration program—and the assurance of additional resources through the imposition of reregistration fees—are intended to ensure that reregistration is completed in a steady and timely manner.

PREREGISTRATION ACCESS TO DATA

Section 3(c)(4) of FIFRA currently provides the public with notice and opportunity to comment on the registration of a pesticide if it contains a new active ingredient or would entail a changed use pattern. However, under section 3(c)(2)(A), data called for in the regis-

tration application are made available to the public, subject to section 10, only after the Administrator registers the pesticide, thus limiting the public's ability to participate effectively in the registration approval process.

The bill would amend section 3(c) of FIFRA to provide the public with access to health and safety data submitted to support an application for the registration of a pesticide. The proposed amendment strikes a balance between the interest of the public in gaining access to health and safety data on pesticides, and the need for adequate protections to prevent the disclosure of research data to commercial competitiors, particularly during the sensitive period before the Administrator acts on an application for a registration. This provision specifically provides that members of the public (excluding pesticide producers) will have access to health and safety data prior to registration of a pesticide in order to review at an early stage the potential environmental effects of the pesticide and to enable the public to evaluate regulatory decisions made by EPA. However, the amendment would prevent the uncontrolled disclosure of certain data, specifically by preventing competitors from obtaining research information to use it for commercial purposes.

To facilitate the process of gaining public access to data, a notice for registration of a pesticide issued by EPA under section 3(c)(4) could include the name and address of the applicant, a statement of the procedure necessary to request access to data, and a brief description of the proposed use and the nature of the active ingredients involved.

Requests for access under the amendment must include an affirmation that the person requesting access is not affiliated with a person engaged in the pesticide business, an identification of any business or other entity on whose behalf the person is acting, if any, and a statement that the person will not intentionally or recklessly violate this provision. The Administrator could require evidence in support of the required affirmation, such as a business or other identification card, or a letter from an employer.

Access to data is to be made available at designated EPA offices (such as regional locations) and at appropriate State agencies that provide adequate safeguards and procedures conforming to section 3, as amended by this provision, of FIFRA. The provision is thus intended to make data readily available to the public at convenient locations while ensuring adequate precautions against unauthorized release of data. The amendment would not authorize preregistration disclosure of or access to the confidential statement of formula.

Data obtained under amended section 3(c) prior to the decision of the Administrator on the application (or subsequently if the application is denied) could not be used in any proceeding of any court or agency of the United States or any State or political subdivision of a State. This provision would not affect the use in such a proceeding of data otherwise obtained through discovery or obtained, pursuant to section 10, after a registration has been granted.

The amendment would allow comments submitted to the Administrator to reasonably quote the data to which access is granted. Comments might be exchanged with other commentators for peer review at any time prior to EPA's decision, within the restrictions

contained in the amendment, including the filing of a request and affirmation with EPA. However, to ensure that data are not delivered to or used by an entity engaged in the production, sale, or distribution of pesticides, comments filed with the Administrator could not be made public before the decision of the Administrator on the application and then disclosed only in a manner consistent with section 10 of FIFRA.

CONDITIONAL REGISTRATION

In 1978, FIFRA was amended to allow conditional registrations of pesticides that lacked a full complement of required data, provided such conditional registrations would not result in the pesticide causing any unreasonable adverse effect on the environment during the period of conditional registration. However, concern has been expressed that, in the past, EPA's implementation of the conditional registration authority has resulted in the use of pesticides that lack adequate health and safety data.

The bill would amend section 3(c)(7) to clarify and limit the use of conditional registrations for additional uses of previously-registered pesticides and for pesticides with new active ingredients. The amendment does not affect existing law with respect to the approval of an application for registration based on health and safety data previously submitted by another registrant ("me-too" registrations).

In addition, the amendment provides that EPA could conditionally amend the registration of a pesticide to permit an additional use only when it finds that to do so will be in the public interest. Conditional amendments to allow additional uses of a pesticide will only be allowed when the applicant has submitted or cited the additional data that the Administrator may require solely for the proposed additional use, such as data regarding residues of the pesticide in food, worker exposure, and environmental fate.

The amendment provides special rules for minor use pesticides, which would include both agricultural and nonagricultural minor uses of a pesticide.

REREGISTRATION OF REGISTERED PESTICIDES

H.R. 2482 would amend the FIFRA to add a new section 3A to establish mandatory time requirements and duties, on both the Administrator and the registrant, in the reregistration of pesticides (see Table that follows). The amendment provides for an accelerated reregistration program. Registrants must review existing data submitted in support of a pesticide registration to determine the adequacy of such data. EPA must also make an independent review of the data to determine their adequacy. The amendment provides that data derived from studies originally submitted before January 1, 1970, will be considered to be inadequate unless the registrant demonstrates to the satisfaction of the Administrator that the data should be considered adequate. In demonstrating the adequacy of the data, the registrant may cite, among other things, consumer experience with the pesticide.

The amendment establishes timetables for the completion of studies (3–48 months) needed for reregistration. Data submission

deadlines imposed by the Administrator should distinguish between different types of tests and their relative complexity. Moreover, these deadlines should parallel the time requirements imposed under EPA's current data call-in procedure under section 3(c)(2)(B). Although the amendment provides that deadlines may be extended in extraordinary circumstances, these circumstances should be limited to the unintentional loss of laboratory results, unintentional destruction of laboratory equipment or facilities, major animal loss, or similarly serious unanticipated occurrences.

Following completion of the required independent review by the Administrator of registrants' submissions of data and information under the reregistration program the Administrator must reregister the pesticide or promptly take other appropriate regulatory actions under FIFRA, such as canceling, suspending, or restricting the pesticide, or imposing label changes.

Consistent with current law and practice, a decision by EPA to reregister a pesticide under proposed section 3A would not restrict the authority of the Administrator subsequently to take any regulatory action with respect to that pesticide otherwise authorized under FIFRA. In addition, proposed section 3A would not affect the Administrator's authority to require additional data to maintain in effect an existing pesticide registration under section 3(c)(2)(B) of FIFRA.

Proposed section 3A would not restrict the authority of the States as provided under section 24 of the Act, to regulate the sale or use of any federally-registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by FIFRA.

Proposed section 3A(f)(1)(I) provides that when a registrant makes a submission under the requirements of section 3A(f), (phase three), the registrant must submit evidence of compliance with the requirements of section 3(c)(1)(D)(ii) of FIFRA and its regulations. The provision, of itself, would not require a person to make a new offer to pay compensation to a data submitter under section 3(c)(1)(D)(ii), but would only require a person to provide evidence of compliance with section 3(c)(1)(D)(ii).

REREGISTRATION PROCESS

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
EPA	REGISTRANT	REGISTRANT	EPA	EPA
o Publish list of pesticide active ingredients subject to reregistration o Ask registrants if they intend to seek reregistration	o Tell EPA of intention to seek reregistration o Identify pesticide's missing and "inadequate" data o Agree to fill data gaps under prescribed deadlines o Pay first portion of reregistration fee	o Summarize and reformat studies to facilitate EPA review o Certify possession of raw data generated by studies o "Flag" adverse data o Pay final reregistration fee	o Independent review of submissions made by registrants under Phases 2 and 3 o Independent indentification of each outstanding data gap revealed in Phases 2 and 3 o Publication of outstanding data gap for each pesticide active ingredient o Issue requirement, as needed, for registrants to fill each data gap	o Thorough examination of all data submitted in support of pesticide reregistration o Reregister pesticide or take other appropriate regulatory action

First List (150 active ingredients)	4 Months	3 Months	9 Months	6 Months	12 Months (+12)
	(4 Months)	(7 Months)	(16 Months)	(22 Months)	(3Y,1M - 7Y,1M)
Second List (150 active ingredients)	7 Months	3 Months	9 Months	12 Months	12 Months (+12)
	(7 Months)	(10 Months)	(19 Months)	(31 Months)	(3Y,10M - 7Y,10M)
Final List (Remaining active ingredients)	10 Months	3 Months	9 Months	21 Months	12 Months (+12)
	(10 Months)	(13 Months)	(22 Months)	(43 Months)	(4Y,10M - 8Y,10M)

(3-48 Months for registrants to conduct required studies)

NOTES: (1) Numbers in parentheses = elapsed time

(2) The three lists above do not include approximately 127 pesticide active ingredients for which EPA has already issued Registration Standards indentifying data requirements. Pesticides involving these 127 active ingredients will be subject to the same requirements imposed on the other active ingredients regarding (a) deadlines for submission of data to EPA; (b) payment of second part of the registration fee; and (c) deadlines for EPA review and reregistration.

REREGISTRATION FEES

The amendment, in proposed section 3A(j), would authorize the imposition of reregistration fees, on a one-time basis per active ingredient, to augment EPA's resources for reregistration and to assist the agency in meeting the timetables mandated in the bill for completion of reregistration. The bill only authorizes the imposition of reregistration fees and would not provide authority for EPA to impose any other type of fees under FIFRA.

While reregistration fees, as provided under the bill, should add substantially to EPA's resources for accomplishing reregistration, additional funds from general revenues may be necessary to complete the reregistration program. Consequently, the Administrator is urged to provide in the agency's future budget requests sufficient resources for the reregistration effort.

The amendment also provides the Administrator with discretionary authority to reduce or waive reregistration fees to maintain the availability of agricultural and nonagricultural minor use pesticides, and to ensure that the cost of the reregistration fee, in and of itself, does not result in the departure of beneficial pesticides or pesticide producers from the marketplace. The Administrator should make annual reports to Congress on the use of this authority, including an identification of the minor use pesticides and individual small businesses that it benefits.

ADMINISTRATOR'S AUTHORITY TO REQUIRE DATA ON INERT INGREDIENTS

Pesticide products contain both active and inert ingredients. In many cases, the inert ingredients may be present in concentrations far greater than the active ingredients. Although inerts are not be used to combat pests, testimony before the Committee has indicated that these chemicals can have adverse effects on the environment.

Last year EPA identified 55 inert ingredients of known "toxicological significance"; another 51 inerts were categorized as "structurally similar" to known carcinogens, teratogens, neurotoxins, or other toxins. For an estimated 800 additional inerts, EPA has little or no toxicity information. The EPA recently began developing a strategy for requiring health and safety data on inert ingredients in pesticides.

The bill would amend section 3(c)(2)(A) of FIFRA to require the EPA to identify and evaluate certain inert ingredients, and order testing where necessary. This directive would keep EPA's current inerts strategy on track.

The priority list of inerts called for in the amendment is intended to be dynamic, with inerts placed on the list in accordance with the specified criteria, and removed from the list as studies are either completed or determined by the agency to be unnecessary. The studies must be completed by registrants, manufacturers, or processors, as the case may be, within a reasonable period of time but not more than 4 years after they are requested by the Administrator. The Administrator may extend the deadline for data submissions by not more than 2 years in extraordinary circumstances—limited to the unintentional loss of laboratory results, un-

intentional destruction of laboratory equipment or facilities, major animal loss, or similarly serious unanticipated occurrences.

The pace at which inerts would resolve on and off the list would be governed by the resources of the agency and the time needed by registrants to develop required data.

The Administrator has identified more than 100 inert ingredients that may meet the listing criteria. Therefore, it is anticipated that the first priority list, to be published in the Federal Register, will include at least 50 inerts. The list at any one time may not contain more than 75 inerts. The list may contain fewer than 50 inerts if the Administrator determines that there is an insufficient number of inerts that meet the listing criteria.

The Administrator should consider non-pesticide uses of inert ingredients in determining what authority to use to require needed health and safety data. For example, the Toxic Substances Control Act (TSCA) might be used if the quantity of the inert ingredient used in pesticides is small in relation to the total quantity produced for all other uses, or if exposure to the environment from the use of the inert ingredient in pesticides is small in relation to exposure from the manufacture, processing, and disposal of the inert ingredient from uses other than in pesticides.

PUBLIC RIGHT TO KNOW

The bill would amend section 7 of FIFRA to provide certain information to the Administrator and the public. The amendment would complement other Federal statutes, and State and local laws that provide increased information to the public about the nature of chemicals to which it may be exposed.

The Committee intends that a Material Safety Data Sheet (MSDS) developed in accordance with the Hazard Communication Standard (29 CFR 1910.1200) be considered generally sufficient to meet the requirements of this provision. However, the Administration may require the supplementation of the MSDS with information as the Administrator may deem appropriate. For example, the Administrator may choose to include environmental data on the fact sheet.

DATA DISCLOSURE TO STATES

The Committee bill would amend section 10 of FIFRA to provide that data or information acquired under the Act may be disclosed by the Administrator under certain conditions, and that the data must be disclosed under other conditions.

In order to receive data under the amendment, a State need not necessarily enact legislation incorporating related provisions currently contained in FIFRA, but the State must assure the Administrator, and the Administrator must determine, that the submitter of the data or information will receive no less protection with respect to disclosure and use by the State than is provided under FIFRA. For example, written confirmation of such protection from a State's attorney general might constitute sufficient assurance for the Administrator to release data to the States.

PUBLIC INTERIM ADMINISTRATIVE REVIEW AND CANCELLATION PROCEEDINGS

The procedures used in the past by EPA in reviewing a pesticide to determine if it may cause unreasonable adverse effects on the environment have been the subject of critical reviews by this and other Committees of Congress, the General Accounting Office, and other interested individuals. EPA's interim administrative review, used to assess the risks and benefits of a pesticide, has been criticized for long delays and inadequate public participation.

The bill would rewrite section 3(c)(8) of FIFRA to streamline and improve EPA's interim regulatory process in several respects, and to eliminate delays in the initiation of a public interim administrative review (Special Review), if such a review is justified. The Administrator is required to establish criteria for initiating a Special Review, based on levels of risk. The Administrator may include consideration of currently available exposure data in the criteria for initiating a Special Review. Lack of exposure data for a pesticide in and of itself would not delay or preclude a Special Review. But a Special Review could be declined on the basis of exposure data alone, only if all relevant means of exposure had been considered. If additional exposure data are needed, registrants may be required to develop the data during the Special Review, as authorized under the Act. Benefits of a pesticide must also be considered in the Special Review.

The amendment provides for public participation in the Special Review and establishes a mandatory schedule for its completion. These procedures are intended to ensure that Special Review decisions, made after consideration of the views of the participating parties, will be made on an objective basis. (See, e.g., "Problems Plague the Environmental Protection Agency's Pesticide Registration Activities," 98th Cong., 2nd Sess., H.R. Rep. No. 98–1147.) This purpose is consistent with the provisions and regulations recently promulgated by the Administrator (40 C.F.R. Part 154) requiring increased public participation and with a recent settlement agreement reached between the EPA and the Natural Resources Defense Council.

Under the amendment, the Administrator must ordinarily give notice of the initiation of a Special Review, a preliminary determination, and a final determination. The Administrator could also adopt regulations to combine or forego any such separate notice, which would provide the agency with flexibility to move directly to a cancellation or suspension hearing if circumstances so require. Full opportunity for public participation in the decision-making process should be preserved where possible.

One objective behind the development of the proposed amendment was the desire to improve the Special Review to enhance the soundness of agency decisions with respect to a pesticide. Consequently, the provision requires that interested persons who participate in the Special Review disclose all scientific data, studies, and expert analyses of those materials in their possession concerning the risks and benefits of the pesticide under review. This provision should not pose an undue burden on registrants or other persons, to require the submission of irrelevant information, or act as an

unreasonable barrrier to those who wish to comment on the agency's proposed actions. However, all pertinent information must be provided by registrants and others to the Administrator in a timely manner.

In order to encourage the full disclosure of data and studies in the Special Review proceeding, the amendment would require that direct testimony of witnesses concerning scientific data or studies that were not, but could have been obtained and submitted in the course of the Special Review by the exercise of due diligence would not be admissable in any subsequent cancellation hearing. However, this limitation is not designed to require the submission of actual testimony concerning the data and studies during a Special Review, or to bar expert opinion or interpretations regarding scientific information during a subsequent hearing.

The bill would amend section 6 of FIFRA to provide any person adversely affected by the decision of the Administrator, following a Special Review, including persons without an economic interest in the pesticide, the opportunity to request a hearing. The amendment responds to a U.S. Court of Appeals' decision on this issue. (See *Environmental Defense Fund* v. *Costle*, 631 F.2d 922 (D.C. Cir. 1980).) Although a person that does not have an economic interest in the pesticide may request a hearing, in order to avoid frivolous requests by such persons, the Administrator must determine that the request presents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment. The person that requests a hearing on an issue will have the burden of going forward to present an affirmative case and have the burden of proof as to that issue.

The bill would amend section 3(c)(6) of the Act to clarify the Administrator's authority to promulgate regulations governing the right to a hearing with regard to denial of an application for registration of a product containing an ingredient that has already been cancelled under section 6.

CHANGES IN LABELING

The Committee bill would amend section 6 of the Act to create new authority for the Administrator to regulate pesticides through certain changes to labeling by informal rulemaking in accordance with Section 553 of the Administrative Procedure Act. This authority does not allow the imposition of labeling changes that are equivalent to a cancellation of use, render the product unmarketable, or otherwise have a major economic impact on persons affected by such changes. Where such circumstances exist, the changes may be made only in the manner and to the extent authorized by other provisions of FIFRA. The amendment contains procedural protections for registrants: the amendment requires a comment period, hearing, opportunity for judicial review, and a stay of the effective date of the regulation if certain criteria are met.

ADMINISTRATIVE CHANGES

The bill would amend section 6 of the Act to clarify that registrants must submit to the Administrator any additional information regarding unreasonable adverse effects on the environment of

a pesticide after its registration to make clear that the information required includes factual information as well as expert opinion regarding risks or benefits.

CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA

In 1976 it was learned that the now-defunct firm of Industrial Bio-Test Laboratories, Inc. (IBT) had provided to registrants large number of reserch studies for numerous pesticides that were the result of careless, falsified, and even fraudulent practices. Eventually it was determined that more than ninety percent of the studies conducted by IBT involving over 200 pesticide active ingredients were affected. Most of these studies have since been replaced or determined to be unnecessary.

In testimony before this Committe, EPA officals have indicated uncertainty over their authority to cancel or suspend registrations where data are found to be false or invalid, since cancellation is authorized only where a pesticide has an unreasonable adverse effect on the environment.

The bill would amend section 6 of the FIFRA to resolve any uncertainty regarding EPA's authority to act in such circumstances. The amendment would require EPA to issue an order of suspension and a notice of intent to cancel the registration of a pesticide in certian cases where data have previously been found to be invalid.

Also under this amendment, if in the future the Administrator determines that invalid data have been submitted in support of a registration (either before or after the effective date of the bill), the Administrator is authorized either to require the submission of valid replacement studies on an expedited basis or, in the alternative, to issue a notice of intent to cancel the registration of the pesticide in question. In making this determination, the Administrator would issue an intent to cancel where such action is in the public interest, considering the scope of the invalid data and the need to use the invalid data to determine whether a pesticide may cause unreasonable adverse effects on the environment. In making a determination the Administration should, for example, consider whether chronic toxicity, oncogenicity, reproductive effects, teratogenicity, or other pivotal studies were invalid. The Administrator's authority to issue a notice of intent to cancel in the case of invalid data is in addition to his existing authority to suspend a pesticide.

This provision would not be used for more conventional outstanding data requirements, questions such as data requirements identified in the reregistration program, where data were initially valid but how simply fail to meet contemporary scientific protocols or changes in regulatory requirements (i.e., they are "indequate" as opposed to "invalid.")

EXPORT OF PESTICIDES

The Committee bill would amend section 2(q)(1) of FIFRA to require that certain precautions be placed on the label of pesticides intended for export, unless such precautions are in conflict with the laws of the importing country.

The amendment defines the term "importing country" for purposes of the notification system established in the amendment to

section 7(a) of the Act to mean the first country to which a pesticide, device, or active ingredient is exported from the United States. In some cases this may not be the country where the pesticide is ultimately sold and used.

The amendment would amend section 17(a) of the Act to modify the notification system by which information on the regulatory status and hazards of certain categories of pesticides is transmitted to foreign countries. The purpose of this amendment is to permit the more complete, efficient, and prompt transmittal of this information, and to cover a larger number of hazardous pesticides. The objective of notification is to enhance the ability of importing countries to make informed decisions about which pesticides can be safely used within their borders.

The key changes made in the current law are as follows:

The notification requirement is expanded to include not only pesticides that are cancelled or not registered, but also those that are suspended, those that are voluntarily withdrawn (if such withdrawal was associated with a concern over potential adverse public health or environmental effects), and those classified for restricted use under Section 3 of the Act. The last category is included because, although restricted use pesticides are legal for use in the United States, they may be hazardous to the environment if improperly used. Information about the reasons for such classification may be just as important to an importing country as the reason for a cancellation or suspension.

The amendment requires that the notification to each country for each pesticide intended for export must be accomplished at least 30 days prior to the first shipment each year of the pesticide to a country. The notification must be delivered, in an appropriate language, to the importer of the pesticide and to the proper government regulatory office in the importing country. A copy of the notice and acknowledgement of its receipt must be delivered to EPA at least 30 days prior to the export of the pesticide.

The amendment requires the party providing notice to obtain written evidence of delivery, and this will be the sole mechanism for demonstrating to the Administrator that the notification was completed. The party providing notice is not required to obtain the consent of the government of the importing country prior to export. Notification, as required in the amendment, gives authorities in the importing country the opportunity to review the information provided by the exporter and take action they may deem appropriate. Since this amendment requires prior notification rather than prior informed consent, the Administrator could not stop or delay exports from the United States to another country because that country failed or refused to accept a notification.

The amendment places an affirmative responsibility on the party who provides notice to obtain written confirmation that the notification was, in fact, delivered. This requirement cannot be met simply by mailing the notification to the appropriate government authority in the importing country. Written evidence of delivery would normally include such documentation as a recipient's signature, a receipt from an international courier service, or a telex answer back form. When such evidence is unavailable, written cer-

tification of delivery by the one who delivers the notice would be acceptable.

Under the proposed notification system, the notification is to be accomplished directly by the exporter. This contrasts with the current notification chain that proceeds from exporter to EPA, to the State Department, to the appropriate American Embassy, and then to the importing country government. The new system should be more prompt and efficient.

Notifications prepared by the exporter may utilize any suitable EPA documents for a particular pesticide. The notifications should make use of information in notices issued under section 17(b) of FIFRA, when available, and the statement required under section 17(a)(3)(E) may include summaries and/or excerpts, fairly presented, of EPA regulatory documents executing the suspension, cancellation and/or restricted use classification, as appropriate. Safeguards will arise from public access to the notifications and EPA review of the notification documents filed with the agency. The amendment also requires that the notification provide the name and address of the EPA office that, upon request, can furnish additional information on both the regulatory action and the particular pesticide.

Proposed section 17(a)(4) requires that labels of pesticides intended for export be written in an appropriate language and prohibits reference to U.S. statutes that would confuse a user of the product. Label translations should inform the ultimate user about the pesticide's proper use and potential hazards, but not interfere with international trade. Thus, under proposed section 17(a)(4)(B) a label reference to compliance with federal and state laws on disposal of pesticide containers should, after translation, actually inform one how containers should be disposed. Similarly, under proposed section 17(a)(4)(A), the appropriate language for purposes of labeling must reach the literate population of the country where the pesticide is to be used without causing an undue burden on international trade. Under certain circumstances, the appropriate language may be English. The appropriate language requirement, in addition to providing obvious health and safety benefits to users, should also be in the exporter's commercial interest by giving meaningful information to users regarding crops, target pests, application rates, and directions for use.

Proposed section 17(a) (2) and (3) of FIFRA is written to become effective 90 days after the date of enactment of the bill, instead of the 60 days provided for the legislation as a whole, in order to permit exporters to prepare for the new notification requirements. The amendment also requires EPA to publish preliminary guidelines to assist exporters with compliance and later to issue regulations.

CERTIFICATION, TRAINING, AND RECORDKEEPING FOR PESTICIDE APPLICATORS

The bill would amend sections 2, 4, 8, and 12 of FIFRA to provide new certification, training, and recordkeeping requirements for applicators and dealers of pesticides. The amendments reflect in part the recommendations of two recent EPA reports: "The Administra-

tor's Pesticide Advisory Committee Labeling Subcommittee Report" (September 1985) and "The EPA Task Force Report on Certification and Training" (August 1985). These reports recommend the establishment and revision of national training materials for certification and registration programs. The reports recommend that existing material be updated and that a number of major, new areas be included, such as chronic health effects, groundwater contamination, endangered species, and pesticide disposal and calibration techniques. The report on certification and training also recommends that minimum competency standards be developed for trainers and non-certified applicators working under the direct supervision of a certified applicator (these non-certified applicators are defined in the amendment as registered or instructed applicators). The report also recommended a mandatory minimum recertification program.

In general, these amendments should be construed in a manner that encourages the states to employ reciprocity for the satisfaction of training requirements in situations where applicators are applying pesticides in more than one state. Reciprocity among the states should be considered an effective means of achieving a consistently high level of competency while encouraging the free flow of commerce across state lines.

In defining the term "principal part" in proposed section 2(e)(1)(A)(ii), it is the intent of the Committee that the Administrator exclude from the commercial applicator category persons engaged in the occasional use of pesticides, but include those persons who use pesticides with such regularity and frequency as to pose a potential threat to public health, the environment, or themselves without the training required of commercial applicators.

LIABILITY

Section 821 of the Committee bill would provide that an agricultural producer will not be liable in any action brought after the effective date of the bill under any Federal statute for damages caused by pesticide use unless the agricultural producer acted negligently, recklessly, or intentionally.

This provision does not establish or imply a right of action for private litigants under FIFRA or any other Federal statue.

The term "agricultural producer" would include the producers of, among other things, food, feed, and fiber commodities, livestock and poultry, fruits and vegetables, tobacco, and forestry, ornamental, nursery, and horticultural groups raised, grown, or produced for commercial purposes.

As provided in the amendment, the term is defined to include non-governmental producers of these items.

A rebuttable presumption that a producer did not act negligently is created on proof that the producer used the pesticide in accordance with label instructions.

DELEGATION AND COOPERATION

Section 4(b)(1) of the Occupational Safety and Health Act of 1970 (OSHA) provides that the Secretary of Labor may not regulate the working conditions of employees where other Federal agencies are

exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. The purpose of Section 4(b)(1) is to prevent duplication of effort among Federal agencies charged with the pretection of workers' safety and health. The bill would amend section 22 of FIFRA to retain the principle of 4(b)(1) of OSHA while making clear that the Department of Labor (DOL) and the Environmental Protection Agency (EPA) should enter into agreements to clarify their respective exercise of statutory authority. The Committee intended that courts must give deference to such agreements.

As an example, EPA might be in the best position to advise applicators on the proper handling of a pesticide, while DOL might be better able to establish safeguards for other workers. When this is the case, and when the agencies can reach an agreement, this subsection would give explicit statutory authority for such an agreement.

WORKER HEALTH AND SAFETY

The Committee bill would amend section 25 of FIFRA to create a mandatory duty for the Administrator to issue regulations (1) to protect employees who mix, load, and apply pesticides and agricultural employees who work in pesticide-treated areas and (2) to train employees who mix, load, and apply pesticides. The content and scope of such regulations must be determined by the Administrator as deemed appropriate and necessary. The amendment provides statutory direction to EPA to proceed with its current efforts to issue farmworker regulations. This subsection is not intended to alter the content or scope of the farmworker regulations currently under review by EPA.

The EPA shall continue to develop and maintain expertise on working conditions and practices of workers exposed to pesticides and use this expertise for such activities as evaluating registration, reregistration, Special Review, and cancellation decisions with respect to effects of such actions on workers health and safety.

STUDY OF NON-AGRICULTURAL PESTICIDES

There is a growing interest in developing Integrated Pest Management (IPM) strategies for urban and suburban non-agricultural pesticide applications, but there is less data available about pesticide use in this area than in agricultural applications.

Prior to setting up an IPM system, it is essential to obtain detailed information about which pesticides are being used, which application patterns are employed, and which pests are being controlled. Once researchers are able to obtain this information they can tell which types of applications are most prevalent for a given pest and which pesticides are being used for control. From that base, alternative measures for intercepting the pest can be devised and new chemical or non-chemical approaches can be integrated into an overall pest control strategy.

This study might be the first step toward the development of a non-agricultural IPM program. It will also provide increased emphasis on aggregate data and use sites for these pesticides at a time when EPA is increasing its scrutiny of them. Furthermore, it will

help develop aggregate exposure data on a variety of pesticides used in homes, offices, restaurants, etc. The study should utilize data already collected for other EPA reports, including: the National Urban Pesticide Applicator Survey, the Report on Golf Course Usage, the Report on Food Establishment Usage, and others. Additional data may also be needed on pesticides sold at the retail level.

DIOXIN STUDY

This provision directs the Administrator to conduct or contract for a study of chlorinated dioxin and dibenzofuran levels in human breast milk in the United States.

The provision is not intended to require that EPA conduct the entire study using agency personnel. Rather, the agency is authorized to coordinate the study while having the actual collection and analysis of the samples performed by a qualified study team under contract with the agency. The study team should consist, at a minimum, of an analytical chemist to analyze the samples, a toxicologist to perform the risk assessment work, and a physician to assess the human health implications, all of whom should have experience in working with chlorinated dioxins and dibenzofurans.

The World Health Organization (WHO) is currently collecting and analyzing human breast milk samples in northern Europe. To the extent practical, the EPA study should be coordinated with WHO in order to determine whether nursing infants in the United States are being exposed to high levels of chlorinated dioxins or dibenzofurans.

The provision directs the Administrator to report to Congress within two years on the study's findings. According to the sponsor of the provision, discussions with various scientists indicate that an adequate two-year study could be conducted for $250,000 annually.

This issue was brought to the Committee's attention after a recent study, extrapolating from mean concentrations of 2,3,7,8-TCDD in body fat samples conducted throughout North America, projected that nursing infants in the United States and Canada could be receiving extremely high levels of dioxin.

GROUNDWATER AUTHORITY

Section 814 of the bill would amend the Act by adding a new section 32 to require the Administrator, where appropriate and necessary, to use the authorities under the Act to provide for the protection of drinking water and groundwater against contamination by pesticides.

Section 814(a) establishes new authority for responding to the detection of pesticides in groundwater.

Section 814(b) requires the Administrator to use, whenever available, maximum contaminant levels established under the Safe Drinking Water Act as groundwater residue guidance levels for the purpose of guiding regulatory action.

Section 814(c) builds on the historic responsibility of states to protect and manage groundwater by requiring the Administrator to consult with and take into account the views of States on key decisions involving appropriate actions under FIFRA to respond to

and prevent contamination of drinking water and groundwater from pesticide use.

Section 814(c)(1) recognizes the distinction between current and potential drinking water in groundwater and groundwater that is not potentially drinking water.

Section 814(c)(2) recognizes that pesticides may degrade in the saturated zone as well as in the unsaturated zone of groundwater, and that this process should be considered in taking action under this section.

Section 814(c)(3) requires the Administrator to consult with the states on the appropriate means of preventing and responding to pesticide contamination of drinking water and groundwater.

Section 814(d) requires the Administrator to consult with the Secretary of Agriculture in carrying out this authority. The provision recognizes that the close cooperation between the Administrator and the Secretary is important to properly regulate pesticides that may be detected in groundwater and in adequately considering the benefits of these pesticides to agricultural users.

SECTION-BY-SECTION ANALYSIS

Section 1—Short title

Section 1 provides that the bill may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986" and supplies a table of contents.

Section 2—References

Section 2 states that, except as otherwise specifically provided in the bill, an amendment or repeal of a section or other provision will be considered to be made to a section or provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("the Act").

TITLE I—PESTICIDE REGISTRATION

Section 101—Preregistration access to data

Section 101(a) would add a new paragraph (9) to section 3(c) of the Act, to provide the public access to data submitted to the Administrator of the Environmental Protection Agency ("the Administrator") to support applications for pesticide registrations.

Subparagraph (A) of new paragraph (9) would require the Administrator to provide public access to health, safety, and environmental data that are submitted or cited in support of an application for the registration of a pesticide containing a new active ingredient or an application for the registration of a pesticide to authorize the initial food use of a previously registered pesticide. The data would be accessible during the period prior to the Administrator's action on the application.

Subparagraph (B) of new paragrpah (9) provides that, to obtain access to the preregistration data, a person must send a request for access and the affirmation described below simultaneously to the Administrator and the registration applicant by certified mail, not later than 30 days after the Administrator publishes a notice of the application for registration.

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Subparagraph (C) of new paragraph (9) provides that the Administrator must grant the request for access to the data unless, within 15 days after the Administrator's receipt of the request and the required affirmation, the applicant submits an objection asserting that the affirmation is inaccurate and the reasons for the objection. The Administrator must determine whether or not to grant the request within 5 days of receipt of a timely objection. If the request is granted, access must not be permitted until 5 days after the applicant making objection has been notified that access has been granted. If the Administrator denies access to the data, comments on the application for which the data were submitted or cited must be filed within 60 days after the date of the decision denying access.

Subparagraph (D) of new paragraph (9) provides that the pre-registration data could be made available only to a person who provides an affirmation, and supporting evidence that the Administrator considers necessary, that the person is not engaged in the production, sale, or distribution of a pesticide, and is neither employed by nor acting directly or indirectly on behalf of a person (or affiliate thereof) engaged in the production, sale, or distribution of a pesticide. The affirmation must identify any business, employer, or other person, if any, on whose behalf the person is requesting the access to data, and state that the person will not intentionally or recklessly violate these provisions. An affiliate of a person is defined as a person who directly or indirectly, through one or more intermediaries, controls or is controlled by or is under common control with the other person. Penalties under section 1001 of title 18 of the United States Code will apply to false statements made in the affirmation.

Subparagraph (E) of new paragraph (9) provides that data supporting an application for registration could be made available to a person only for the purpose of permitting the person to comment to the Administrator on the application. Comments submitted to the Administrator could reasonably quote the data, but no person, including the Administrator, could make the comments public prior to a decision by the Administrator on the application for registration (or after the decision if the application is denied). Except as described below in this paragraph, a person who obtains data under new paragraph (9) (directly or indirectly) could not publish, copy, or transfer the data to any other person for use to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world, or use the data for any purpose before any court or government agency prior to the Administrator's decision to approve the registration (or after the decision, if the application for registration is denied). Preregistration data and comments could be disclosed, consistent with provisions of the Act that protect trade secrets and other information, after registration of the pesticide.

Subparagraph (F) of new paragraph (9) provides that the preregistration data could be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by new paragraph (9), but could not be removed from the office. The Administrator must maintain a record of the persons who inspect the data and a copy of this record must be sent to the data submitter upon request.

Subparagraph (G) of new paragraph 9 provides that, once access to preregistration data is granted, the data could be examined and notes on the data could be taken for use in developing comments on the application for registration. Comments on the application must be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended an additional 30 days by the Administrator for good cause.

Section 101(b) would amend section 3(c)(4) of the Act to require the Administrator to publish notice of an application for the registration of a pesticide not later than 30 days after receipt and provide a 60-day comment period on the application. Section 3(c)(4) currently requires that a notice of application be published "promptly" and provides for a 30-day comment period.

Section 102—Criminal penalties for disclosure of information

Section 102 would amend paragraph (3) of section 14(b) of the Act to provide that any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 of the Act, which would include the new preregistration access to data provisions under section 101, will be fined not more than $25,000, or imprisoned for not more than 3 years, or both. Current law provides a fine of not more than $10,000 and the same maximum prison term.

Section 102 also would add a new provision to paragraph 3 of section 14(b) of the Act providing that any person (including any officer, contractor, or employee of the United Sates or a State) who is granted preregistration access to data and, in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, knowingly violates the preregistration access to data provisions under section 101, or knowingly allows data to be made available in violation of those provisions, will be fined not more than $100,000, or imprisoned for not more than 3 years, or both.

Section 103—Conditional registration

Section 103 would amend section 3(c)(7) of the Act by rewriting and modifying subparagraphs (B) and (C) regarding conditional registrations.

New subparagraph (B) contains provisions, like current law, authorizing the Administrator to conditionally amend the registration of a pesticide to permit additional uses of the pesticide, notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (1) the applicant has submitted or cited the additional data required solely for the proposed additional use; and (2) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment. However, new paragraph (B) will add a third requirement for the conditional registration—that the additonal use is in the public interest.

New subparagraph (B), similarly to current law, further provides that no registration of a pesticide could be amended to permit an additional food or feed use of the pesticide during the pendency of any evaluation by the Administrator initiated by a notice stating

that the pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under the provisions of the Act (section 3(c)(8)) relating to public interim administrative reviews. The Adminstrator could amend the registration of a pesticide to add a minor food or feed use, notwithstanding that notice has been issued that the pesticide may meet or exceed the risk criteria, if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is no effective alternative pesticide available that does not meet or exceed the risk criteria.

New subparagraph (B), similarly to current law, would require an applicant seeking an amended registration to submit or cite data that would be required to obtain a registration of a similar pesticide under the Act. If the applicant is unable to submit or cite an item of data because it has not yet been generated, the Administrator could amend the registration of the pesticide under conditions that will require the submission or citation of the data no later than would be allowed for the maintenance of the registration of the similar pesticide under the Act.

New subparagraph (B) contains a provision not in current law that, if data concerning chronic dosing, oncogenicity, reproductive effects, mutagencity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide, and if a reasonably sufficient period of time has elapsed for the generation and submission of the data since the data requirement was first imposed, a conditional amendment to permit an additional use of the pesticide for other than a minor use could not be granted unless the data have been submitted.

New subparagraph (C) would restate current provisions of law to allow the Administrator to conditionally register a pesticide containing an active ingredient not contained in any registered pesticide for a period of time reasonably sufficient for generation and submission of required data that have not been submitted because a period of time reasonably sufficient for the generation of the data has not elapsed since the data requirement was imposed. Any such registration would be subject to (1) the conditions that by the end of the period the Administrator receives the data and the data do not meet or exceed risk criteria associated with human dietary exposure specified in regulations under the provisions of the Act (section 3(c)(8)) relating to public interim administrative reviews; and (2) other conditions that the Administrator may prescribe. A conditional registration could be granted only if the Administrator determines that use of the pesticide during the period will not cause any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest. If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of the pesticide and a period reasonably sufficient for generation of such data has elapsed since the data requirement was first imposed by the Administrator, then a conditional registration of the pesticide otherwise available under new subparagraph (C) could not be granted unless the data have been submitted.

Section 104—Definition of outstanding data requirement

Section 104 would amend section 2 of the Act by adding a new subsection (ff) to define the term "outstanding data requirement." Under the new definition, the term means a requirement for any study, information, or data necessary to make a final registration determination under the Act that has not been submitted to the Administrator, or if submitted, that the Administrator determines must be resubmitted because it is not valid, complete, or adequate to make a final registration determination. In determining whether a study is valid, complete, or adequate, the Administrator must examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

Section 105—Reregistration of registered pesticides

Section 105(a) would add, after section 3 of the Act, a new section 3A to provide for the reregistration of pesticides.

Subsection (a) of new section 3A would provide a general rule requiring the Administrator to reregister, in accordance with new section 3A, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide that the Administrator had determined after November 1, 1984, and before the effective date of these provisions, that there are no outstanding data requirements and the other requirements for registration under the Act have been met.

Subsection (b) of new section 3A would require the Administrator, not later than one year after the date of enactment of the bill, by order, to issue guidelines to be followed by registrants in summarizing studies, reformatting studies, identifying adverse information, and identifying studies that have been submitted that may not meet the registration requirements of the Act or its regulations. The guidelines would not be subject to judicial review. The Administrator must monitor the progress of registrants in acquiring and submitting data required by section 3A.

New subsection (b) also would establish penalties for certain violations of new section 3A. It would require the Administrator to issue a notice of intent to suspend the registration of a pesticide, in accordance with the procedures provided by section 3(c)(2)(B) of the Act, if the Administrator determines that progress is insufficient to ensure the submission of the data required under a commitment within the time period required under section 3A, or if the registrant fails to submit the data within the time period. A notice of intent to suspend also must be issued if the Administrator determines that tests necessary to fill an outstanding data requirement have not been initiated within one year after the issuance of a notice for additional data under section 3A. If the Administrator determines that progress is insufficient to ensure submission of the data necessary to fill an outstanding data requirement within the prescribed time period or if the required data have not been submitted to the Administrator within the time period, the Adminis-

trator would issue a notice of intent to suspend the registration. The Administrator also would issue notice of intent to suspend if a registrant otherwise fails to comply with the provisions of section 3(c)(2)(B), which relate to how registrants are to provide additional data to support an existing registration.

A registrant who submits a false certification under subsection (b) of new section 3A will be considered to have violated the Act and be subject to the civil and criminal penalties under section 14 of the Act.

Subsection (c) of new section 3A provides an outline of the phases under which pesticides will be considered for reregistration under section 3A:

Phase one would include the listing of the active ingredients of pesticides that must be reregistered.

Phase two would require the submission to the Administrator by registrants of (1) notices respecting their intention to seek reregistration; (2) identification of missing an inadequate data; and (3) commitments to replace the missing or inadequate data within the applicable time period.

Phase three would include the submission of certain information supporting the reregistration of the pesticide.

The fourth phase would include an independent initial review by the Administrator of the submission required under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requirements to submit additional data.

Phase five would include the review by the Administrator of data submitted for reregistration and appropriate regulatory action by the Administrator.

Subsection (d) of new section 3A provides for phase one of the reregistration of pesticides. Under these provisions, the Administrator would list the active ingredients of pesticides to be reregistered giving priority to active ingredients (other than active ingredients of pesticides for which registration standards have been issued before the date of enactment of the bill) that, among others: (1) are in use on or in food or feed and may result in postharvest residues; (2) may result in residues of potential toxicological concern in potable groundwater, edible fish, or shellfish; (3) have been determined by the Administrator before the date of enactment of the bill to have significant outstanding data requirements; or (4) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

Subsection (d) would require the Administrator, by order, (1) not later than 70 days after the date of enactment of the bill, to list pesticide active ingredients for which registration standards have been issued; (2) not later than 4 months after date of enactment, to list the first 150 pesticide active ingredients from the priority list described above; (3) not later than 7 months after date of enactment, to list the second 150 of the pesticide active ingredients from the priority list; and (4) not later than 10 months after date of enactment, to list the remainder of the pesticide active ingredients from the priority list. Each of the lists must be published in the Federal Register. The content of the lists would not be subject to judicial review.

The Administrator must notify, by certified mail, registrants of pesticides that contain active ingredients that are published on a list at the time of publication. This notice would specify when registrants must notify the Administrator of their intention to seek or not to seek reregistration.

Subsection (e) of new section 3A, phase two of reregistration, provides, as a general rule, that each registrant of a pesticide that contains an active ingredient listed for reregistration, and not included on the list of pesticide active ingredients with registration standards, must (within the time period described below) submit a notice of intent to seek or not to seek reregistration and any information, commitment, or offer, as described below. (NOTE: Pesticide active ingredients with registration standards would be listed separately and would not be subject to all of the requirements under the preliminary phases of section 3A.)

Specifically, the registrant must notify the Administrator by certified mail whether or not the registrant intends to seek reregistration of the pesticide. If the registrant notifies the Administrator of an intention not to seek reregistration, the Administrator must publish a notice of this fact in the Federal Register. A registrant must notify the Administrator within three months after the publication of the list that includes the active ingredient. The Administrator could extend this period if factors beyond the control of the registrant prevent compliance with the period prescribed.

Subsection (e) provides that each such registrant who submits a notice of intention to seek reregistration must submit, in accordance with regulations issued under the registration provisions of the Act, an identification of (1) all data required to support registration with respect to the active ingredient, (2) data previously submitted by the registrant in support of the registration of the pesticide that are inadequate, and (3) data not submitted but required for reregistration.

In addition, the registrant would have to submit either (1) a commitment to replace or submit the inadequate or missing data within a reasonable time determined by the Administrator (but not more than 48 months, unless extended by the Administrator by no more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the prescribed period); or (2) an offer to share in the cost to be incurred by a person who has made a commitment to replace or submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to sharing in the cost of the data.

Subsection (e) provides that data are inadequate for the above purposes if the data are derived from a study with respect to which the registrant is unable to make a certification that the registrant possesses or has access to the raw data used in or generated by the study. Further, data will be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that the data should be considered to support the registration of the pesticide.

Subsection (e) would also provide sanctions for registrants that do not comply with its requirements. If a registrant does not submit a notice of intention to seek or not seek reregistration not

later than 3 months after the listing of the pesticide active ingredient, the Administrator must issue a notice of intent to cancel the registration of the registrant for the pesticide. The notice of intent to cancel must be published in the Federal Register and 60 days allowed for comments. After such 60 days, the Administrator, by order and without further hearing, could cancel the registration or take other action, including extension of the time period, as may be needed to allow the reregistration of the pesticide by another person.

If no registrant of a pesticide containing an active ingredient listed for reregistration notifies the Administrator that the registrant intends to seek reregistration of any pesticide containing that active ingredient, or if no registrant complies, as required under phase two, with the requirements for identification of missing and inadequate data and submission of a commitment to replace the missing or inadequate data within the applicable time period, or if the required reregistration fee has not been paid, then the Administrator must publish in the Federal Register a notice of intent to remove the active ingredient from the reregistration list and a notice of intent to cancel the registrations of all pesticides containing the active ingredient. The Administrator must provide 60 days for comments on the notice. After the 60-day comment period, the Administrator, by order, could cancel any of the registrations without a hearing. However, the Administrator could not cancel a registration under this provision if, during the comment period, a person acquires the registrant's rights in the registration and furnishes a notice of intent to reregister the pesticide, and not later than 120 days after publication of the notice of intent to cancel, the person complies with the other requirements of phase two and pays the reregistration fee.

Subsection (f) of new section 3A provides for phase three of reregistration. Each registrant who has submitted, under phase two, a notice of intent to seek the reregistration of a pesticide active ingredient listed for reregistration, not including pesticide active ingredients with registration standards, must submit within 12 months after listing and in accordance with the guidelines issued by the Administrator—

(1) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient and considered by the registrant to be adequate to meet the requirements of the registration provisions of the Act and its regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;

(2) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient that may not comply with the registration provisions of the Act and its regulations, but that the registrant asserts should be deemed to comply with the regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;

(3) a reformat of the data from each study summarized as described above concerning chronic dosing, oncogenicity, repro-

ductive effects, mutagenicity, neurotoxicity, or teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(4) where data that are to be so reformatted are not required for the active ingredient by the regulations issued under the registration provisions of the Act, a reformat of acute and subchronic dosing data sumitted by the registrant before January 1, 1982, that the registrant considers to be adequate to meet the requirements of the registration provisions of the Act and its regulations;

(5) an identification of data that are required to be submitted to the Administrator as indicating an adverse effect of the pesticide under proposed new section 6(g)(4) of the Act, to be added by section 305 of the bill;

(6) an identification of any other information available that in the registrant's view supports the registration;

(7) either a commitment to submit data to fill each outstanding data requirement identified by the registrant, within a reasonable period of time determined by the Administrator but not more than 48 months (unless the Administrator extends this period by not more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the 48-month period), or an offer to share in the cost of developing the data to be incurred by a person who has made a commitment to submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to cost sharing; and

(8) evidence of compliance with the data compensation provisions of the Act and its regulations with regard to previous submitted data as if the registrant were now seeking the original registration of the pesticide.

Subsection (e) provides sanctions for registrants that fail to comply with the requirements of phase three. If the registrant of a pesticide fails to submit the information required under phase three within the prescribed time period, the Administrator, by order and without hearing, must cancel the registration of the pesticide.

If the registrant submits the phase three information within the time period prescribed but the information does not conform to the guidelines for submissions established by the Administrator, the Administrator must determine whether the registrant made a good-faith attempt to conform to the guidelines. If the Administrator determines that the registrant make a good-faith attempt to conform to the guidelines, the registrant will be provided a reasonable time to make necessary changes or corrections. If the Administrator determines that the registrant did not make a good-faith attempt to conform, a notice of intent to cancel the registration would be issued, and sent to the registrant by certified mail. The registration will be canceled without a hearing of further notice 30 days after the registrant receives the notice unless a hearing is requested by the registrant. A hearing would be conducted under the hearing provision of section 6(d) of the Act, except that the only matter for resolution at the hearing would be whether the registrant made a good-faith attempt to conform its submission to the

guidelines. The hearing must be held and a determination made within 75 days after the receipt of the request for a hearing.

Subsection (g) of new section 3A would provide for phase four of reregistration. The Administrator must review the submissions of all registrants made under phases two and three of reregistration with regard to an active ingredient to determine if all data concerning that ingredient that are missing or inadequate were identified. The Administrator could require registrants to submit complete copies of studies summarized under phase three.

Subsection (g) also would require the Administrator to independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient listed under phase one that is contained in a pesticide to be reregistered (other than any pesticide active ingredient for which registration standards have been issued). The Administrator, at the same time, must issue notice under section 3(c)(2)(B) of the Act to require the submission of additional data necessary to meet the outstanding data requirements. The Administrator must take the actions required under phase four, in the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the first group of 150, not later than 18 months after the date of the listing. For a pesticide containing an active ingredient without a registration standard, listed under phase one in the second group of 150, the Administrator must take the actions required under phase four not later than 24 months after the date of listing. In the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the last group of active ingredients to be reregistered, the Administrator must take the actions required under phase four not later than 33 months after the date of the listing.

New subsection (g) would provide that, if the Administrator issues a notice to a registrant under phase four for the submission of additional data, the registrant must submit the data within a reasonable period of time determined by the Administrator (but not to exceed 48 months after issuance of the notice). The Administrator, on application of a registrant, couuld extend this period by no more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the prescribed period.

Subsection (h) of new section 3A would provide for phase five of reregistration. Under subsection (h), the Administrator must conduct a thorough examination of all data submitted under the reregistration provisions for each active ingredient, and all other available data found by the Administrator to be relevant. Within one year after the submission of all data concerning an active ingredient submitted under subsection (g), the Administrator must determine whether pesticides containing the active ingredient are eligible for registration. For extraordinary circumstances, the Administrator could extend such period for up to one additional year.

Before reregistering a pesticide, the Administrator must obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B). The Administrator must require that the product-specific data be submitted not later than eight months after it is determined that a pesticide is eligible for reregistration, unless the

Administrator determines that a longer period is required for generation of the data. The Administrator then must review such data within 90 days after its submission.

Under subsection (h), after conducting the required reviews, the Administrator must determine whether to reregister a pesticide by determining if the pesticide meets the registration requirements of the Act. If the Administrator determines that a pesticide is eligible to be reregistered, then it must be reregistered within six months following the date all required product-specific data were submitted for the pesticide. If after conducting the required reviews the Administrator determines that a pesticide should not be reregistered, the Administrator must take appropriate regulatory action.

Subsection (i) of new section 3A contains provisions for compensation of data submitters under section 3A for use of such data. Subsection (i) provides that the existing data compensation provisions of section 3 of the Act will apply to data submitted by a registrant under phases two through five that are used to support the application for registration of another person under section 3. In determining the amount of compensation, fees paid by the registrant for reregistration must be taken into account.

Subsection (j) of new section 3A would provide for the payment of reregistration fees. This subsection provides that registrants of pesticides that contain an active ingredient listed under phase one (other than any active ingredient that has been the subject to a registration standard) that is an active ingredient of any pesticide registered for a major use on food or feed must collectively pay an initial fee of $50,000 on submission of the information under phase two. Registrants of the above described pesticides must collectively pay a final fee of $100,000 on submission of data or other information concerning the active ingredient under phase three.

Subsection (j) provides that registrants of pesticides that contain an active ingredient listed under phase one for which a registration standard *has* been issued and that is contained in any pesticide registered for a major use on food or feed must collectively pay a fee of $100,000 at a time prescribed by the Administrator.

Subsection (j) provides that registrants of pesticides containing an active ingredient listed under phase one for reregistration (not including those active ingredients with registration standards) that is not contained in any pesticide registered for a major use on food or feed must collectively pay fees in an amount determined by the Administrator. The fees could not be less than one-half of, nor greater than the above-described fees for pesticides registered for a major use on food or feed. Such fees would be paid at the same time as the above-described fees.

Registrants of pesticides, listed under phase one, contianing an active ingredient for which a registration standard *has* been issued and that is not contained in any pesticide registered for a major use on food or feed must collectively pay a fee of not more than $100,000 and not less than $50,000 at a time prescribed by the Administrator.

Under subsection (j), in the case of an active ingredient of a pesticide that is registered solely for an agricultural or nonagricultural minor use or in the case of a pesticide the value or volume of use of which is small, the Administrator, on application, could reduce or

waive the fees described above. In the case of an antimicrobial active ingredient for which the production level does not exceed 1,000,000 pounds per year, the Administrator, on application, could reduce or waive the fees described above.

In the case of a small business registrant that produces an active ingredient of a pesticide, the Administrator, on application, could reduce or waive the fees described above. A small business registrant is defined as a corporation, partnership, or unincorporated business that has 125 or fewer employees, and for the last 3 years before the application for a reduction or waiver had an average annual gross revenue that did not exceed $20,000,000.

Subsection (j) provides that, on payment of fees in accordance with the above described provisions, the Administrator could not levy any other fees for reregistration with respect to that active ingredient.

If two or more registrants are required to pay a fee with respect to a particular active ingredient, the fees for the active ingredient must be apportioned among the registrants on the basis of the market shares of domestic sales of the active ingredient for the preceding three calendar years. The Administrator, by order, could require a registrant to submit a report to allow the Administrator to apportion fees under this provision.

If any required apportionment report is not submitted by a registrant after receiving notice, or if any fee is not paid on time, the Administrator, by order and without hearing, could cancel each registration held by the registrant of a pesticide containing the active ingredient involved. The Administrator then must reapportion the fee among the remaining registrants and notify the registrants that they are required to pay any unpaid balance of the fee within 30 days after receipt of the notice.

Subsection (k) of new section 3A provides that the requirements of phases two, three, and four and the fee requirements of section 3A will not apply to any person who is the registrant of a pesticide to the extent that, under the exemption provided under section 3(c)(2)(D) of the Act, the person would not be required to submit or cite data to obtain an initial registration of the pesticide under section 3.

Subsection (l) of new section 3A would establish in the Treasury of the United States a reregistration fund. Reregistration fees collected by the Administrator would be deposited into the fund and be available to the Administrator, without fiscal year limitation, to carry out the reregistration provisions. Money in the fund not currently needed to carry out reregistration activities could be maintained on hand or on deposit, invested in obligations of, or guaranteed by, the United States, or invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds. The Administrator would be required to provide an annual accounting of the fees collected and disbursed from the fund and take all steps necessary to ensure that the expenditure of the funds are used only to carry out the reregistration provisions.

Subsection (m) of new section 3A provides that any failure of the Administrator to take any action required under the reregistration

provisions of section 3A will be subject to judicial review under section 16(b) of the Act.

Section 105(b) would make a technical amendment to repeal subsection (g) of section 3 of the Act (which provides only that the Administrator must accomplish reregistration in the most expeditious manner possible, giving priority to pesticides that leave postharvest residues on crops).

Section 105(c) would amend section 2 of the Act by adding a new subsection (gg) to define the term "antimicrobial". Under the new definition, the term means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) disinfectants intended to destroy or irreversibly inactiviate bacteria, fungi, or viruses on surfaces or inanimate objects;

(2) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air;

(3) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture; or

(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces.

Section 105(c) also would amend section 2(u) of the Act to include in the definition of the term "pesticide" any substance or mixture of substances intended for any of the antimicrobial purposes describes in clauses (1) through (4) of the preceding paragraph.

Section 106—Administrator's authority to require data on inert ingredients

Section 106(a) would amend section 3(c)(2)(A) of the Act to provide that, if the Administrator requires additional information about an inert ingredient to support the registration of a pesticide, a sufficient time must be permitted for registrants to obtain the information.

Section 106(b) would amend section 3 of the Act by adding a new subsection (g) to direct the Administrator to establish a priority list of: (1) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under the Act; (2) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect, and that have significant use in pesticides or to which there is significant exposure from pesticides; and (3) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, if the pesticide is one to which there is significant exposure.

The priority list must be published by the Administrator not later than 90 days after the effective date of the bill. Revisions to the list must be published annually. The priority list, any inert in-

gredient's inclusion on or exclusion from the list, or any revision to the list would not be subject to judicial review.

The priority list must consist of not less than 50 inert ingredients unless the Administrator determines that there are fewer than 50 inert ingredients that meet the requirements for inclusion on the list. The list may not exceed 75 inert ingredients.

New subsection (g) also would require the Administrator to determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list described above. Section 106(b) would require the Administrator to demand each registrant of the pesticide, or manufacturer or processor of the inert ingredient under the Toxic Substances Control Act, to submit the data. The data must be submitted within a reasonable time but not later than four years after the request, unless the Administrator extends the period by not more than two years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the data. Data requirements imposed, or a decision not to require data for an inert ingredient, would be subject to judicial review under procedures provided in section 16(b) of the Act.

On receipt of additional data the Administrator must, within one year, evaluate the data and take appropriate steps to prevent unreasonable adverse effects on the environment caused by pesticides that contain the inert ingredient. Under exceptional circumstances, the Administrator could extend the evaluation period by not more than one year.

New subsection (g) states that it should not be construed to affect any other authority of the Administrator to regulate impurities, contaminants, degradants, or other ingredients of pesticides that have been deliberately added; to regulate any deliberately added inert ingredient that has not previously been used in a pesticide, or a significant new use of the inert ingredient in a pesticide; to require the submission of short-term environmental fate or residue studies for deliberately added inert ingredients; or to require the submission of revised formula statements under section 3(c)(2)(B) of the Act.

The Committee intends that subsection (g) be construed in a manner that does not affect the authority of the Administrator to regulate ingredients that are not deliberately added to pesticides. More specifically, it is the Committees's intent that the Administrator remain free to regulate ingredients that are not deliberately added under whatever authorities are available. Thus, the presence of any particular ingredient on the priority list established under subsection (g) should not be a basis for the Administrator not proceeding under other authorities. By the same token, however, the Committee intends that the Administrator exercise sound judgment in deciding whether to proceed under this subsection or under other existing authorities. In this fashion, the Committee expects the Administrator to weigh the regulatory options available and choose those most consistent with the objectives of the bill while accommodating the reasonable concerns of registrants about unnecessarily duplicative approaches.

Section 106(b) also will amend section 3(c)(1)(D) of the Act to clarify that data submitted in support of the safety of an inert ingredient would be subject to the data compensation provisions of the Act (as limited by the exclusive use provisions of such section) for the 15-year period following the date the data were originally submitted.

Section 107—Definition of ingredient statement

Section 107 would amend section 2(n) of the Act to redefine the term "ingredient statement" to mean a statement that contains (1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients in the pesticide; (2) the name of each inert ingredient in a pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the use pattern and concentration level of the inert ingredient in the pesticide; (3) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic; (4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and (5) the name of any inert ingredient for which the Administrator has required additional data under new subsection (g)(5) of section 3 because the inert ingredient is listed in new subsection (g)(1), as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under the Act.

NOTE.—The definition, under current law, consists only of the items described in clauses (1) and (3) of the preceding sentence.

Section 108—Disclosure of inert ingredients

Section 108 would amend section 10(d) of the Act to allow the disclosure of information on inert ingredients in ingredient statements.

Section 109—Compensation for data on inert ingredients

Section 109 would rewrite the provisions of section 3(c)(2)(D) of the Act (which contains the so-called "formulator exemption") to add a new requirement that no applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide will be required to offer to pay reasonable compensation otherwise required by the Act for a study concerning the inert ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.

TITLE II—INFORMATION DISCLOSURE

Section 201—Public right to know

Section 201(a) would amend section 7 of the Act by adding a new subsection (e) to require any producer operating a pesticide production establishment in any State to prepare or obtain a fact sheet for each active ingredient manufactured or used at the establish-

ment. The producer must maintain copies of the fact sheet at the establishment and furnish a copy to any person on request.

Each fact sheet must contain the chemical name, each common name, and any trade name of the active ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient. Fact sheets must be revised as often as is necessary to reflect current information about the active ingredient. The Administrator could require a fact sheet to be amended to provide accurate and clear information to the public.

Each producer must furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes the name of each ingredient for which a fact sheet is required that is manufactured or used at each establishment operated by the producer, and the location of each establishment where the ingredient is manufactured or used by the producer, and a copy of the most current fact sheet. Fact sheets and annual reports must be made available to the public.

The Committee intends that a Material Safety Data Sheet (MSDS) developed in accordance with the Hazard Communication Standard (29 CFR 1910,1200) will be considered generally sufficient to meet the fact sheet requirements of new subsection (e). However, the Administrator could require the supplementation of the MSDS with such information as the Administrator deems appropriate. For example, the Administrator might choose to include environmental data on the fact sheet.

Section 201(b) would amend section 7)d) of the Act to provide that information about pesticide production locations submitted to the Administrator is not to be considered confidential or subject to the trade secrets provisions of the Act.

Section 202—Data disclosure to States

Section 202(a) would amend section 10 of the Act by adding a new subsection (h) to allow the Administrator to disclose to a State any data or information acquired under the Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided under the Act (see paragraph (1) of new subsection (h).

New subsection (h), in paragraph (3), would require the Administrator to disclose such data or information to any State based on such assurances if the State makes the further assurance, and the Secretary determines, that the law of the State allows the submitter to recover just compensation in a civil action against the State for losses that result from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or 10 of the Act.

Paragraph (2) of new subsection (h) provides that, for purposes of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code, the disclosure or use by a State of data or information, provided by the Administrator under paragraph (1), in a manner inconsistent with section 3 or 10 of the Act must be considered a taking of property

and the act of the State will be considered an act of the United States.

Section 202(b) would redesignate section 31 of the Act as section 33 and add a new section 31 regarding the collection, dissemination, and use of data. Under these provisions, the Administrator must establish, administer, and be responsible for the continuing activities of an agency committee that will design, establish, and coordinate an efficient system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies or States, and the use of the data submitted to the Administrator under the act. The Administrator must ensure the completion of the design and implementation of the system and required procedures within 36 months after the effective date of the bill. The agency committee must solicit advice from data users outside the Federal Government through means of a permanent advisory committee that will consist of representatives from private groups, State governments and organizations, and industry, and other representatives as may be appropriate.

New section 31 also would require the Administrator, in consultation and cooperation with the Secretary of Agriculture and other heads of appropriate Federal and State departments and agencies, to design, establish, and coordinate an efficient and effective system for the retrieval of pesticidal, toxicological, and other scientific data that could be useful to the Administrator in carrying out the Act. Systematized retrieval must be developed for use by all Federal and State departments and agencies with responsibilities in the area of regulation or study of pesticides and their effect on men and the environment.

New section 31 provides that, in designing and implementing the required systems, the Administrator will be required to index information by pesticide name, Chemical Abstracts Service registry number, establishment site, and submitter, so that information can be retrieved in a timely and useful manner.

The Administrator would be required to report to Congress, within 24 months after the effective date of the bill, on progress made in designing and implementing specified systems for information management. The report must address the handling of information submitted before the effective date of the bill, as well as the procedures established to ensure that information collected after such data will comply with new section 31.

The dissemination of information and data collected under new section 31 to any State would be protected by the trade secrets provisions of the Act.

Title III—Review and Cancellation

Section 301—Public interim administrative review

Section 301(a) would rewrite paragraph (8) of section 3(c) of the Act, which deals with public interim administrative reviews.

Subparagraph (A) of new paragraph (8) provides that, in general, a public interim administrative review to determine whether the use of a pesticide (including a category of pesticides) may pose unreasonable adverse effects to humans or the environment must be conducted in accordance with new paragraph (8).

Subparagraph (B) of new paragraph (8) would require the Administrator to set forth, in published regulations, the criteria for initiating a public interim administrative review. The criteria must be based on levels of risk and could include consideration of currently available exposure data. The absence of exposure data must not delay or preclude initiation of a public interim administrative review. The Administrator could decline to initiate a review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

Subparagraph (C) of new paragraph (8) would restate existing law (current paragraph (8)), which provides that the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of the pesticide under the Act unless the public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

Subparagraph (D) of new paragraph (8) provides that, on receipt of information about a pesticide demonstrating that the criteria for initiating a public interim administrative review have been met, the Administrator must immediately notify all registrants of the pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met. Not later than 30 days after receipt of the notice, a registrant could respond to the notice. Not later than 60 days after the Administrator provides a notice, the Administrator must determine whether a public interim administrative review of the pesticide will be initiated.

Subparagraph (E) of new paragraph (8) would require that, if the Administrator intends to initiate a public interim administrative review of a pesticide registered for agricultural uses, the Administrator notify the Secretary of Agriculture of the intention to initiate the review and the reasons for the review.

Subparagraph (F) of new paragraph (8) would establish procedures for the public interim administrative review. Any public interim administrative review must be initiated and conducted in accordance with regulations published by the Administrator. The regulations must provide that a public interim administrative review include a notice of initiation of the review and opportunity for public comment on the notice, a notice of the Administrator's preliminary determination and opportunity for public comment thereon, and a notice of final determination. The regulations could authorize the Administrator to combine or forgo any of the above notices. Any proposed determination of the Administrator must be submitted to the Scientific Advisory Panel at its next scheduled meeting for comment solely on relevant scientific issues. The public would be allowed to submit comments to the Scientific Advisory Panel on the scientific issues.

Under subparagraph (F), the notice of the initiation of a public interim administrative review or the notice of preliminary determination must state the basis for the review or determination and include a request for any additional data needed, and a bibliography of all scientific data and studies, and expert analysis, concerning

the risk or benefits of the pesticide that are under review. Information in the bibliography must be made available to the public consistent with the trade secrets provisions of the Act. The Administrator must determine, to the extent feasible, before the initiation of the review which data in the bibliography could be disclosed to the public under the Act. If the Administrator receives additional data concerning the risk or benefits, the bibliography must be revised within 30 days and made available to the public.

Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments could be submitted on the review or determination. Any person who submits comments must disclose to the Administrator all scientific data and studies, and analyses, in the person's possession concerning the risks or benefits of the pesticide that are under review that were not included in the bibliography in the notice. New scientific data, studies, and expert analyses of the data must be disclosed to the Administrator by such person within 30 days after he receives them.

Subparagraph (F) would require the Administrator to decide, not later than 18 months after the initiation of a review, which regulatory action (if any) to take and publish the decision.

The time limits specified for the review could not be extended, except in exceptional circumstances in which (1) additional data critical to a fair and accurate determination of risks posed by the pesticide are required; (2) the extension is for a period limited to the time required to obtain the data on an expedited basis and in no event to exceed one year; and (3) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for the data at that time.

Subparagraph (G) of new paragraph (8) would allow any person to seek judicial review under section 16(a) of the Act for failure of the Administrator to act within a required time period.

Section 301(b) would make a conforming amendment to section 25(d) of the Act, regarding submissions under new paragraph (8) to the Scientific Advisory Panel.

Section 301(c) provides that the amendments made to section 3(c)(8) of the Act will apply only to public interim administrative reviews initiated after January 1, 1987.

Section 302—Proceedings under section 6

Section 302 would amend section 6 of the Act (administrative review and cancellation) by redesignating subsection (f) as subsection (i) and adding a new subsection (f) to provide special procedures for public hearings resulting from a public interim administrative review.

Paragraph (1) of subsection (f) provides that the special rules described below will govern a hearing that results from the Administrator's final determination in a public interim administrative review that (1) is initiated after January 1, 1987, (2) includes an opportunity for comment on a notice of preliminary determination, and (3) for which the time between the first public notice for the review and the close of the last comment period for the review is not less than 180 days. Otherwise, the provisions of subsection (d)

of section 6 (as revised by section 304 of the bill) will govern such hearings.

Paragraph (2) of new subsection (f) provides that any person who is adversely affected by a decision of the Administrator respecting a pesticide, including a person without an economic interest, following a public interim administrative review could request, or intervene in, a hearing (in the manner provided by subsection (b)(2)(B) of section 6 (as added by section 303 of the bill)) within 30 days after the decision. The party would have to identify with particularity the disputed findings or conclusions of the decision and include a complete statement of the reasons and factual basis for the request. A person could request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with the procedural provisions of section 3(c)(8) governing public interim administrative reviews (as added by section 301(a) of the bill).

Paragraph (3) of new subsection (f) provides for certain procedures to be followed at a hearing following a public interim administrative review. Under these provisions, at the request of a party, the administrative law judge conducting the hearing could receive into evidence portions of the review record and other evidence that the party demonstrates are relevant and material to the disputed issues and are not unduly repetitious, if a competent witness is made available to be cross-examined on all matters relating to the evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the review proceeding by the exercise of due diligence would not be admissible at the hearing. The right of other parties to confront and cross-examine witnesses would be preserved with respect to material issues of adjudicative fact, so long as the cross-examination is not unduly repetitious.

Paragraph (3) also provides that, not later than 120 days after the administrative law judge is appointed, prehearing matters must be completed and the hearing begun. The administrative law judge could establish a schedule for prehearing matters, including prehearing discovery and motions, and must ensure that the hearing schedule is met. The administrative law judge must issue appropriate orders for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision. Further discovery would be permitted after such 120-day period only on a determination by the administrative law judge that (1) the discovery would not in any way unreasonably delay the proceeding, (2) the information to be obtained is not otherwise obtainable, and (3) the information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

Paragraph (3) states that any challenge to the authority to issue, or the procedural correctness of the issuance of, any notice of intent to cancel or change classification, or to any request for a hearing or motion to intervene, must be filed with the administrative law judge before the evidentiary phase of the hearing. Not later than 30 days before the hearing begins, the parties must exchange witness lists, a brief narrative summary of expected testi-

mony, and a list of all documents and exhibits expected to be introduced at the hearing. Thereafter, witnesses, documents, or exhibits could be added and narrative summaries of expected testimony amended by motion.

If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and if necessary, could submit the studies to the Scientific Advisory Panel for supplemental comment on an expedited basis (and under time limits set by the judge).

The administrative law judge must schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that this schedule is not to prejudice the right of a party to present evidence. The person who requested a hearing on an issue will have the burden of going forward to present an affirmative case and have the burden of proof on that issue.

Under paragraph (3), a hearing must be completed and the Administrator must make a final decision within 300 days after the issuance of the notice of the final determination (under the public interim administrative review procedure) that gave rise to the hearing. This overall time limit could not be extended, except in exceptional circumstances in which it is essential for a fair and accurate determination of pivotal facts central to the proceeding, and in no event by more than an additional 180 days. Other time limits under paragraph (3) could be extended for good cause. Failure to complete a hearing and make a final decision within 300 days will be grounds for a civil action in a district court of the United States to seek an order to establish a schedule requiring the prompt completion of the hearing, but will not be grounds for termination of the hearing or for making a final decision respecting the pesticide.

Section 303—Cancellation and change in classification or labels

Section 303 would rewrite and modify subsection (b) of section 6 of the Act, which contains procedures for cancellation and change in classification (under current law, it contains no specific provisions relating to label changes).

Paragraph (1) of new subsection (b) would restate existing law that if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator can issue a notice of intent (1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the action of the Administrator; or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed. The notice of the intent of the Administrator must be sent to each registrant of the pesticide and be made public. In determining whether to issue the notice, the Administrator must include among those factors to be taken into account the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

Not later than 60 days before sending the notice to a registrant or its being made public, whichever occurs first, the Administrator must provide the Secretary of Agriculture with a copy of the proposed notice and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture must provide comments on the notice and analysis to the Administrator within 30 days after receipt. If the Secretary of Agriculture provides comments in writing within 30 days, the Administrator must publish in the Federal Register (with the notice) the comments of the Secretary and the response by the Administrator. If the Secretary of Agriculture does not provide comments in writing within 30 days, the Administrator can notify the registrant and make public the notice at any time after the 30-day period. The time requirements can be waived or modified to the extent agreed upon by the Administrator and the Secretary of Agriculture.

If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator can waive the requirement of notice to the Secretary of Agriculture and submission to the Scientific Advisory Panel and proceed in accordance with the suspension provisions of subsection (c) of section 6.

Paragraph (2) of new subsection (b) would restate and add to existing law to provide that the action proposed in the notice of intent will become final and effective at the end of 30 days after receipt by the registrant or publication, whichever occurs later, unless within that time the registrant makes the necessary corrections, if possible, or a request for a hearing is made by a person adversely affected by the notice.

New requirements would be imposed if a request for a hearing is made. Specifically, the request would have to identify with particularly the findings and conclusions of the decision of the Administrator that are disputed, and include a complete statement of the reasons and factual basis that support the request for a hearing. Any party to the proceeding would be allowed to identify findings and conclusions in dispute.

As under existing law, if a hearing is held pursuant to a request, or the determination of the Administrator to hold a hearing, a decision pertaining to registration or classification issued after completion of the hearing will be final.

Under a new provision, before convening a hearing on the request of a person without an economic interest in the pesticide, the Administrator would have to determine that the request presents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment. Only if the Administrator made a determination that the request presents such an issue would the Administrator be required to convene a hearing.

Paragraph (3) of new subsection (b) would restate existing law that in taking any action to issue a notice of intent to cancel a registration, change its classification, or hold a hearing to determine whether or not the registration should be cancelled or its classification changed, the Administrator must consider (1) restricting uses of the pesticide as an alternative to cancellation and fully explain the reasons for the restriction; and (2) the impact of the action on production and prices of agricultural commodities, retail food

prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of the impact.

Paragraph (4) of new subsection (b) contains new provisions for pesticide label changes that could be required by the Administrator through informal rulemaking. The Administrator could require label changes, under these provisions, by informal rulemaking, unless the proposed changes are equivalent to a cancellation of use, render the product unmarketable, or otherwise have a major economic impact on persons affected by the changes. If the Administrator is so precluded from making the proposed label changes, the Administrator could require the changes only through another proceeding authorized by the Act.

Under paragraph (4), the Administrator could notify the registrant of the proposed label change and provide for comments by the registrant during a 30-day period beginning on the date of the registrant's receipt of the notice. If the registrant notifies the Administrator that the registrant does not object to the proposed label change, then the change will take effect as prescribed by the Administrator. If the registrant does not submit comments to the Administrator in the 30-day period, the Administrator must notify the registrant that, if the registrant does not submit comments within 30 days after the second notice, the registration will be cancelled without a hearing or further notice. If the registrant objects, the Administrator can proceed further only as described in the preceding paragraph.

Paragraph (4) also provides that, if a regulation is promulgated that requires a label change, the Administrator must notify each registrant of the pesticide subject to the regulation and provide a 30-day period for each registrant to apply for an amendment to the registration to comply with the regulation. If a registrant does not apply for an amendment within the 30-day period, the Administrator must issue a notice of intent to cancel the registration in accordance with paragraph (2). Such notice of intent to cancel will be deemed to have been issued under paragraph (1), described above, for purposes of the paragraph (2) hearing procedures.

A registrant or user of a pesticide subject to the regulation could request a hearing on the regulation in accordance with paragraph (2). The scope of the hearing would be limited to (1) whether the pesticide complies with the regulation; (2) whether the regulation by its terms is applicable to the pesticide; and (3) whether, because of significant information that was not (and could not reasonably have been) presented in the rulemaking proceeding, it would be unreasonable to require the pesticide to comply with the regulation.

Paragraph (4) would require a court, in an action for review of the regulation under section 16(e) of the Act, on request, to postpone the effective date of the regulation until completion of the review action if the petitioner shows a likelihood of success on the merits in the action, and that implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner. However, the court could not postpone the effective date of the regulation if the Administrator shows that failure to implement the regulation would cause a risk of substantial harm to health or the environment.

Section 304—Public hearings and scientific review

Section 304 would amend section 6(d) of the Act, which contains procedures for the conduct of hearings initiated under section 6(b) of the Act, to delete provisions relating to referrals of questions of scientific fact to a committee of the National Academy of Sciences.

Section 304 also would amend section 6(d) of the Act to provide that, as soon as practicable after completion of the hearing, but not later than 18 months after the issuance of the notice that gave rise to the hearing, the Administrator must evaluate the data and reports before him and (1) issue an order revoking the section 6(b) notice of intent, or (2) issue an order either cancelling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. (Note: Under current law, the Administrator has only 90 days to so act.) Also, a new provision would be added to section 6(d) to permit the time period to be extended by the Administrator under extraordinary circumstances for not more than one year.

Section 305—Administrative changes

Section 305(a) would amend section 6 of the Act to provide certain general provisions in a new subsection (g). Under new subsection (g), a registrant, at any time, could request that any of its pesticide registrations be cancelled or amended to delete one or more uses. Before acting on the request, the Administrator would be required to publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator could approve the request.

New subsection (g) also would specifiy that a notice of denial of registration, notice of intent to cancel, notice of suspension, or notice of intent to suspend issued under the Act, certain other notices under the registration provisions of new section 3A (to be added by section 105(a) of the bill), and a second notice of a label change under paragraph (4) of section 6(b) (to be added by section 303) must be published in the Federal Register and sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice after making reasonable efforts to do so, the notice will be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

New subsection (g) essentially would restate existing law (now contained in subsection (a) of section 6) with respect to existing stocks of canceled pesticides. It provides that the Administrator could permit the continued use, the continued distribution or sale, or both, of existing stocks of a pesticide whose registration is cancelled under any provision of the Act to the extent, under conditions, during periods, and for uses as the Administrator may specify if the Administrator determines that the distribution, sale, or use is not inconsistent with the purposes of the Act and will not cause unreasonable adverse effects on the environment.

New subsection (g) would restate and clarify existing law (now contained in section 6(a)(2)) that, if at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the information must be submitted to the Administrator. The term "information" is defined to include factual information and expert opinion regarding risks or benefits. (See also the analyses of section 305(b)(2) below.)

Section 305(b)(1) would amend section 3(c)(6) of the Act to provide that if the Administrator issues a notice of the denial of registration, a request for a hearing under section 6 of the Act (as authorized under current law) must be made within 30 days after the receipt of the notification. The Administrator would be authorized to issue regulations governing the right to a hearing with respect to the denial of any application for the registration of a product containing a ingredient that was cancelled under section 6. Under the regulations, due weight must be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings. The notice requirements of new subsection (g) of section 6 (to be added by section 305(a)) regarding publication of a notice of the denial of a registration would apply to section 3(c)(6) denials.

Section 305(b)(2) would amend section 6(a) of the Act by striking out section 6(a)(2). The paragraph to be struck, which requires registrants to submit, to the Administrator, additional factual information regarding unreasonable adverse effects of a pesticide, would be relocated in new subsection (g) of section 6 (to be added by section 305(a)).

Sections 305(b)(2) and 305(b)(3) would strike out language in sections 6(a)(1) and 6(e)(1) of the Act that provide authority for the Administrator to allow the continued use, distribution, or sale of existing stocks of a pesticide whose registration is cancelled. These provisions would be combined in new subsection (g) of section 6 (to be added by section 305(a)).

Section 306—Suspension and cancellation of registration based on false or invalid data

Section 306 would amend section 6 of the act by adding a new subsection (h) to require the administrator to immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if, prior to the effective date of the bill, the Administrator has previously determined in the Industrial Biotest validation process that data submitted by a registrant in support of the registration were invalid and (1) have not been replaced or (2) are in the process of being replaced on the effective date of the bill, but have not been submitted by April 1, 1988; and (3) are material to the registration. The term "Industrial Biotech test validation process" refers to a United States-Canada cooperative effort, begun in the late 1970s, to review studies by Industrial Biotech Laboratories, Inc., to determine their value.

New subsection (h) further would specify that, if after the effective date of the bill, the Administrator determines that invalid data are submitted by a registrant in support of a registration, the Administrator could (1) require the registrant to submit valid re-

placement studies or data on an expedited schedule and to submit interim progress reports, or (2) issue a notice of intent to cancel the registration if the administrator determines that it would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

Also under new subsection (h), if a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator must immediately issue notices of intent to suspend and cancel the registration.

New subsection (h) would establish procedures for hearings on the cancellation or suspension of a registration based on false or invalid data. Any suspension or cancellation under subsection (h) would become final and effective 30 days after receipt by the registrant of a notice issued thereunder unless, during the 30-day period, a request for a hearing is made by a person adversely affected. The hearing would be conducted in accordance with section 6(c) suspension or 6(d) cancellation hearing procedures, as appropriate.

The only matters for resolution at a hearing with regard to data involving the Industrial Biotest validation process would be whether (1) in response to a notice issued by the Administrator under section 3(c)(2)(B) (calling in additional data to support the registration), data previously determined to be invalid have not been replaced as of the effective date of the bill or were in the process of being replaced on the effective date but were submitted to the Administrator by April 1, 1988, and (2) the data are material to the registration. The only matters for resolution at a hearing regarding data submitted in support of registration and determined to be invalid after the effective date of the bill would be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment. The only matters for resolution at a hearing regarding a determination that a registrant willfully submitted material data known to be false in support of a registration would be whether the registrant willfully submitted material data known to be false.

A decision made after completion of any of the above types of hearings will be final. Any such hearing must be held and a determination made under subsection (h) within 75 days after receipt of a request for the hearing.

Section 307—Tolerances for agricultural commodities

Section 307 would amend section 408 of the Federal Food, Drug, and Cosmetic Act (which contains provisions relating to the establishment of tolerances for residues of pesticide chemicals in or on raw agricultural commodities) to add a new subsection (p). Under new subsection (p), if the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has—

(1) been cancelled by the Administrator under the Act;

(2) voluntarily been cancelled under the Act; or

(3) voluntarily been withdrawn under the Act,

due in whole or in part to risks to humans, the Administrator would be required, not later than 60 days after the effective date of

the cancellation or after receipt of information of the withdrawal, to revoke any tolerance for residues of the pesticide in or on the commodity, or any exemption from the need for a tolerance, as established under section 408. In revoking a tolerance or an exemption from a tolerance, the rulemaking procedures under section 553 of title 5 of the United States Code must be used.

The effective date of a revocation of a tolerance could be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of the use of the cancelled pesticide before the date of its cancellation, the use of existing stocks of the pesticide as authorized under the order cancelling the registration of the pesticide, or unavoidable residual environmental contamination.

Also, under new subsection (p), if the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under the Act due in whole or in part to risks to humans, the Administrator, not later than 60 days after the effective date of the suspension, must suspend any tolerance for residues of the pesticide chemical in or on the commodity, or exemption from the need for tolerance, as established under section 408.

The effective date of the suspension could be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of the use of the suspended pesticide before the date of its suspension, the use of existing stocks of the pesticide as authorized under the order suspending the registration of the pesticide, or unavoidable residual environmental contamination.

In suspending a tolerance or an exemption from a tolerance, the rulemaking procedures of section 553 of title 5 of the United States Code must be used.

The suspension of a tolerance or an exemption from a tolerance for a pesticide chemical must be effective as long as the registration of the pesticide is suspended. If the registration of the pesticide ceases to be suspended and is not cancelled, the Administrator must rescind any suspension of the tolerance or exemption.

Under new subsection (p), at the time the Administrator makes the determination whether a pesticide is eligible for reregistration or should be reregistered, under phase five of the reregistration provisons of new section 3A of the Act (to be added by section 105(a) of the bill), any tolerance for residues of the pesticide chemical or any exemption from the need for a tolerance established under section 408 must be reassessed and established, amended, or revoked as necessary.

Section 307(b) makes a conforming amendment to subsection (m) of section 408.

Title IV—Records and Inspections

Section 401—Records

Section 401(a) would amend section 8 of the Act to rewrite and modify subsection (a) and delete subsection (b). Existing subsection

(b) would be reincorporated into section 9 of the Act by section 402 of the bill.

Section 8, as rewritten, would retain the substance of current subsection (a) and add related new provisions. Under new subsection (a) of section 8, the Administrator would be authorized to require, by regulation, any pesticide producer, exporter, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility (a new term defined under section 401(b) of the bill), or commercial applicator, or any person who distributes or sells any pesticide, to (1) prepare, and maintain for reasonable periods of time, records that the Administrator finds necessary for the effective implementation or enforcement of the Act; (2) furnish to the Administrator reports stating the location where the records are maintained; and (3) furnish copies of the records to the Administrator on written request. Except as provided in new subsections (c), (d), and (e) of section 8 (to be added by section 601(c) of the bill) relating to applicator certification and training, the Administrator could not require any person who distributes or sells at retail a non-restricted use pesticide to prepare, maintain, or furnish any record for that pesticide under new subsection (a).

Under new subsection (b), the Administrator could not require any person to maintain records of: (1) financial data, sales data, or pricing data; (2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to the exposure; or (3) research or test data (other than data relating to registered pesticides, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).

Section 401(b) would amend section 2 of the Act to add a new subsection (hh) defining the term "pesticide testing facility". Under the new definition, the term means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing it). The term would not include any person solely on account of the person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under the Act.

Section 401(c) would make amendments to section 26(c) of the Act to conform with the amendments made by sections 401 and 402 of the bill.

Section 402—Inspections

Section 402(a) would rewrite subsection (a) of section 9 of the Act, which currently provides general authority for the Administrator, in enforcing the Act, to enter premises and inspect and obtain samples of pesticides. New subsection (a), as rewritten by section 402(a), would retain the substance of the first sentence of current subsection (a), add provisions (currently in section 8) relating to copying

of records, and add related new provisions. The last five sentences of current subsection (a) would be deleted, but the matters they cover would be included in new subsection (d) of section 9, to be added by section 402(c) of the bill. Under new subsection (a), officers or employees of the United States or of any State, duly designated by the Administrator will be authorized, at reasonable times, to (1) enter any place where any pesticide, active ingredient, or device is distributed or sold to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at the place or of any packaging or labeling of the pesticide, active ingredient, or device; (2) enter any place where there are located any records required by the Act, including any place reported under new subsection (a) of section 8, to be added by section 401(a) of the bill, as a location where records are maintained, to inspect and obtain copies of the records; (3) enter any pesticide testing facility (a new term defined under section 401(b) of the bill) to inspect the facility and the testing being conducted at the facility and inspect and obtain copies of any records required by the Act to be maintained by the pesticide testing facility; and (4) enter any place where the officer or employee has reason to believe that the Act has been or is being violated by any person other than a private applicator, to inspect the place and obtain evidence of the violation.

Section 402(b) would rewrite subsection (b) of section 9 of the Act, which deals with entry, inspection, and seizure warrants. Under new subsection (b), authority would be provided for officers or employees of the United States or of any State, duly designated by the Administrator, to obtain and to execute warrants authorizing (1) entry for the purposes of section 9, as revised by the bill; (2) inspection and copying of all records required under the Act; and (3) seizure of any pesticide or device that is in violation of the Act. New subsection (b) retains the substance of current subsection (b), as implemented by the Environmental Protection Agency.

Section 402(c) would amend section 9 of the Act by adding a new subsection (d) relating to the procedures to be followed before entry or inspection of premises is made. The provisions of new subsection (d) are similar to those of the last three sentences of current section 8(b) (to be deleted under section 401(a)) and the last five sentences of current section 9(a) (to be deleted under section 402(a)).

Specifically, new subsection (d) provides that, before making any entry or inspection of any premises not open to the general public under section 9, as rewritten, the person conducting the inspection must present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the inspection and whether a violation of the Act is suspected. Each entry or inspection must be commenced and completed with reasonable promptness. If the person conducting the entry or inspection obtains any samples of pesticides or devices before leaving the premises, the person must leave with the person in charge a receipt describing the samples and, if requested and practicable, a portion of each sample equal in volume or weight to the portion retained. If an analysis of the sample is made a copy of the results of the analysis must be furnished on request to the person in charge of the premises.

Section 402(c) also would add a new subsection (e) to section 9, requiring the Administrator to coordinate actions taken under section 9 with actions taken under other Federal laws to avoid duplicate inspections.

TITLE V—EXPORT OF PESTICIDES

Section 501—Definition of misbranded

Section 501 would amend section 2(q)(1) of the Act, which defines the term "misbranded" by listing a number of situations in which a pesticide would be considered misbranded. The amendment made by section 501 would add a new provision to the list in section 2(q) to provide that a pesticide intended for export and substantially similar in composition and use pattern to a registered pesticide will be misbranded if the label is not written in an appropriate language, as required by new subsection (a)(4)(A) of section 17 of the Act (to be added by section 503(a) of the bill), or does not contain the same health, safety, and hazard precautions as the pesticide registered under the Act unless the precautions on the label are in conflict with laws of the importing country.

Section 502—Definition of importing country

Section 502 would amend section 2 of the Act to add a new subsection (ii) to define the term "importing country". Under the new definition, the term means the first country to which a pesticide, device, or active ingredient subject to the notification requirements of new subsection (a) of section 17 of the Act (to be added by section 503(a) of the bill) is exported from the United States.

Section 503—Pesticides and devices intended for export

Section 503(a) would rewrite and modify subsection (a) of section 17 of the Act, which imposes requirements applicable to exported pesticides. Paragraph (1) of new subsection (a) provides that, notwithstanding any other provision of the Act, no pesticide, device, or active ingredient used in producing a pesticide intended solely for export to any foreign country will be considered in violation of the Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of the pesticides, devices, and active ingredients used in producing pesticides will be subject to provisions of the Act that—

(1) define lable and labeling;

(2) provide that a pesticide is misbranded under certain conditions;

(3) require the registration of establishments;

(4) provide for records and recordkeeping; and

(5) in new subsection (a), regulate pesticides and devices intended for export.

This provision is the same as existing law, except that exporting producers would also be made subject to the misbranding provisions of section 2(q)(1)(I) of the Act, to be added by section 501 of the bill.

Paragraph (2) of new subsection (a) would restrict the export of a pesticide, device, or active ingredient (1) for which a restricted use classification has become effective; (2) for which a cancellation or

suspension has become effective; (3) the registration of which has been voluntarily withdrawn by the registrant, if the withdrawal is associated with concern over potential adverse public health or environmental effects; or (4) that is not registered for any use. Export of the pesticide, device, or active ingredient described above would be allowed only if, at least 30 days before the first shipment each year, the exporter (1) provides notice in accordance with paragraph (3) to the person importing the pesticide, device, or active ingredient and the appropriate government regulatory office in the importing country; (2) receives written evidence that the notice was delivered to the appropriate government regulatory office; and (3) submits a copy of the notice (in English) and evidence of delivery to the Administrator. Such documents would be made available to the public on request.

Paragraph (3) of new subseciton (a) provides that the notification required by paragraph (2) must be made in an appropriate language and contain the—

(1) name of the pesticide and the common and chemical names of the active ingredients;

(2) name and address of the person exporting the pesticide, device, or active ingredient;

(3) name and address of the person importing the pesticide, device, or active ingredient;

(4) name and address of the appropriate government regulatory office in the importing country;

(5) reasons why the registration was cancelled, suspended, voluntarily withdrawn, or classified for restricted use (and the list of restrictions) or a statement that the pesticide ingredient is not registered in the United States; and

(6) name and address of the office of the Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

Paragraph (4) of new subsection (a) would require that the label of pesticides intended for export from the United States be written in an appropriate language. Labels of pesticides intended for export could not refer to compliance with the laws of the United States, except for a statement (required under section 2(q)(1)(H) of the Act) that the pesticide is "Not Registered for Use in the United States", unless the label also cotains or is accompanied by a description of the relevant requirements of the law.

Section 503(b) provides that the export restrictions and notification provisions of paragraphs (2) and (3) of new subsection (a) will become effective 90 days after the date of enactment of the bill. Section 503(b) also provides that, not later than 30 days after the date of enactment of the bill, the Administrator must publish in the Federal Register a list of the names, addresses, and the international telecommunications codes of appropriate regulatory offices required to receive notices under paragraph (2). Not later than 180 days after the date of enactment, and annually thereafter, the Administrator must revise the list of regulatory offices of importing countries designated to receive notices.

Section 503(b) also would require that, not later than 90 days after the date of enactment of the bill, the Administrator must

publish in the Federal Register preliminary guidelines regarding the form of notification under new subsection (a), translation of the notification and labels required, preparation and retention of records by exporters, and procedures for public access to documents submitted by exporters.

Section 504—Cancellation notices furnished to foreign governments

Section 504 would rewrite subsection (b) of section 17 of the Act retaining the substance of current law and adding related provisions. New subsection (b) would require the Administrator promptly to transmit through the Secretary of State a notice to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever (1) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective, or (2) a pesticide is classified for restricted use. Such notice also must be retransmitted annually to the office or agency described above.

The contents of the notice must include (1) the reasons for the regulatory action taken; (2) for cancelled or suspended registrations, information concerning other registered pesticides that could be used in lieu of the pesticide; and (3) the name and address of the office of the Environmental Protection Agency that on request can provide additional information on the pesticide.

Section 505—Cooperation in international efforts

Section 505 would revise and expand subsection (d) of section 17 of the Act to require the Administrator to—

(1) in cooperation with the Secretary of State, other appropriate Federal agencies, and nongovernmental and international organizations, actively participate in international efforts to develop and improve pesticide research and regulatory programs;

(2) provide foreign countries with technical assistance to develop comprehensive pesticde regulatory programs;

(3) within one year after the effective date of the bill, and every three years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to ascertain what procedures exist in each country (a) regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides, and (b) to control residues on foods to meet tolerances established under United States law; and

(4) report annually to Congress on such activities.

Title VI—Certification and Training

Section 601—Certification, training, and recordkeeping amendments

Section 601(a) would revise section 2(e) of the Act, which contains definitions relating to persons who apply pesticides. As revised, section 2(e) provides that—

(1) the term "commercial applicator" is to mean a person (whether or not the person is a private applicator with respect to some uses) who (a) uses or supervises the use, for any pur-

pose or on any property, of any pesticide that is classified for restricted use; (b) uses or supervises the use of any pesticide for hire as the principal part of the person's business or work; or (c) (as an employee of a person that uses or supervises the use of any pesticide for hire as the *principal part* of the person's business or work) uses or supervises the use of any pesticide. The term does not include a person who uses or supervises the use of a pesticide as a private applicator. It is the intent of the Committee that, in defining the term "principal part" in implementing this definition, the Administrator exclude from the commercial applicator category persons engaging in the occasional use of pesticides, but include those persons who use pesticides with such regularity and frequency as to pose a potential threat to the public health, the environment, or themselves without the training required of commercial applicators;

(2) the term "private applicator" is to mean a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the person or the person's employer or on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) the term "certified applicator" is to mean a commercial or private applicator who is certified under section 4 of the Act (which will be substantially amended under section 601(b)); and

(4) with respect to the term "under the direct supervision of a certified applicator", unless otherwise prescribed by its labeling, a pesticide is to be considered to be applied under the direct supervision of a certified applicator if it is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though the certified applicator is not physically present at the time and place the pesticide is used.

The new definitions of "private applicator" and "under the direct supervision of a certified applicator" are substantially the same as existing law. The new definition of "certified applicator" revises the current definition in the first sentence of section 2(e)(1) to reflect the other changes in the Act made by title VI. The second sentence of section 2(e)(1) is deleted, but substantially retained in the definition of "to distribute or sell" in new subsection (kk) of section 2, to be added by section 802(a) of the bill. The new definition of "commercial applicator" would expand the definition in current law by adding the provisions described in clauses (b) and (c) of item (1) above.

Section 601(a) also would amend section 2 of the Act to add a new subsection (jj) to define the term "pesticide dealer". Under new subsection (jj), the term means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or is designated by the Administrator, by regulation under new subsection (d)(2) of section 8 of the Act (to be added by section 601(c)), as a pesticide that may cause significant adverse effects on health or the environment. The term does not include a person who only distributes or sells pesticides that are classified for general use and not so designated by the Adminis-

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trator, by regulation, as pesticides that may cause significant adverse effects on health or the environment.

Section 601(b) would amend section 4 of the Act (which deals with the use of restricted use pesticides and the certification of applicators) by adding new subsections (d) through (l).

New subsection (d) provides rules with respect to the training and certification of commercial applicators.

Under paragraph (l) of new subsection (d), it would be a violation of the Act for any person to use any pesticide as a commercial applicator unless the person is a certified commercial applicator, or a registered commercial applicator under the direct supervision of a certified applicator who is a certified commercial applicator.

Under paragraph (2) of new subsection (d), to be considered to be a *certified* commercial applicator, a person must at a minimum—

(1) have met the standards prescribed under subsection (a) of section 4 of the Act and have received training prescribed by the State agency responsible under section 4 for administering certification activities in the State involved (including training using material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g) of section 4 (to be added by section 601(b)) and conducted by a trainer who has met requirements under new subsection (h) of section 4 (to be added by section 601(b)) that satisfies the minimum standards for training programs under new subsection (h);

(2) have field, institutional, or industrial experience in pesticide use and application;

(3) have passed an examination prescribed by the State agency; and

(4) possess a valid commercial applicator certification issued by the State agency.

Under paragraph (3) of new subsection (d), to operate as a *registered* commercial applicator, a person at a minimum must have received training prescribed by the State agency (including training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g)) conducted by a trainer who has met requirements under new subsection (h), and possess a valid registration issued by the State agency. A person could obtain a registration by providing to the State agency a report, signed and dated by the trainer and the person who received the training, stating that the prescribed minimum training has been provided and received.

New subsection (e) provides rules with respect to the certification and training of private applicators.

Under paragraph (1) of new subsection (e), a restricted use pesticide would be considered to have been applied by or under the direct supervision of a certified private applicator only if it is applied by a person who is either a certified private applicator, or a supervised private applicator who uses a pesticide under the direct supervision of a certified private applicator.

Under paragraph (2) of new subsection (e), to be considered to be a *certified* private applicator a person at a minimum must have (1) met the standards prescribed under subsection (a) of section 4 and have received training prescribed by the State agency (including

training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g)), conducted by a trainer who has met requirements under new subsection (h), that satisfies the minimum standards for training under new subsection (h), and (2) possess a valid private applicator certification issued by the State agency.

Under paragraph (3) of new subsection (e), to be considered to be a *supervised* private applicator a person at a minimum must have received basic instruction prescribed by the State agency or based on material prescribed by the State agency or based on material prescribed by the State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling. The training must be given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the minimum standards for trainers under new subsection (h). The State agency could require the employer of a supervised private applicator to confirm that the basic instruction described above has been received.

New subsection (f) deals with recertification and reregistration. New subsection (f) would require each certified applicator and each registered commercial applicator within a State to undergo refresher training and be recertified or reregistered within a period established by the State agency but not to exceed 5 years. The refresher training must be prescribed by the State agency and include training in the materials established by the Administrator in cooperation with the Secretary of Agriculture under new subsection (g) and in the relevant requirements of the other subsections of section 4 and section 3(d) (classification of pesticides), section 12 (unlawful acts), and section 14 (penalties) of the Act. To be *recertified,* an applicator at the minimum must meet the requirements of paragraph (2) of new subsection (d) (other than the examination requirement) or the requirements of paragraph (2) of new subsection (e), as applicable. To be *reregistered,* a commercial applicator must meet the requirements of paragraph (3) of subsection (d).

New subsection (g) deals with applicator training. New subsection (g) would require the Administrator in consultation with the Secretary of Agriculture to develop training material on the use of appropriate procedure for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling. Within 12 months after the effective date of the bill, the Administrator, in consultation with the Secretary of Agriculture, must revise and make current the materials and thereafter update as needed.

New subsection (h) deals with minimum standards for trainers and training materials.

Paragraph (1) of new subsection (h) would require the Administrator to establish, within one year after the effective date of the bill, minimum standards of competency, and experience or expertise, for trainers referred to in new subsection (d), and minimum standards for the training programs referred to in subsection (d). The training programs under subsection (d) must comply with the minimum standards established by the Administrator within two years after the effective date of the standards. If after the two-year period, a State's training program fails to meet the minimum standards, or if a State fails to prescribes the program, the Administrator must notify the State of the failure. After receipt of the notice, a State will have 90 days to bring its training program into compliance with the standards, after which time, if the program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (d).

Under paragraph (2) of new subsection (h), the Administrator must establish (within two years after the effective date of the bill) minimum standards of competency, and experience or expertise, for trainers referred to in new subsection (e), and minimum standards for the training programs referred to in subsection (e). Training programs prescribed by any State under subsection (e) must comply with the minimum standards not later than two years after the effective date of the standards. If on the expiration of such two-year period a State's training program fails to meet the minimum standards, or if a State fails to prescribe the program, the Administrator must notify the State of the failure. After receipt of the notice, a State would have 90 days to bring its training program into compliance with the standards. If after the 90-day period the State's training program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (e) for use in the State.

New subsection (i) deals with privately administered training programs. Under new subsection (i), a State agency could approve any privately administered training program that it determines meets the requirements established under section 4, or requirements established by the State agency, whichever are more stringent.

New subsection (j) deals with enforcement officer training. New subsection (j) provides that Federal and State field personnel responsible for on-site observations and inspections of pesticide use must have training that, as a minimum, includes training covering materials specified in new subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

New subsection (k) provides that in establishing standards under section 4 applicable to applicators, the Administrator must establish separate standards for commercial applicators and private applicators.

New subsection (l) provides that, for the purposes of section 4, the term "State agency" means the agency of a State that is designated in the State certification plan under subsection (a) of section 4 as the agency responsible for administering the plan throughout

the State, if the State has primary enforcement responsibility for pesticide use violations as provided for under section 26 of the Act. In the case of a State that does not have primary enforcement responsibility or that does not have an agency designated in the State plan, a reference to a State agency would be considered a reference to the Administrator.

The amendments to section 4 made by section 601(b) would be phased in as follows:

Subsection (d): Except as provided below, the provisions of new subsection (d) would take effect in a State on the expiration of the two-year period prescribed by new subsection (h) (within which training programs of the State are to be in compliance with minimum standards prescribed by the Administrator—which the Administrator will have one year after the effective date of the bill to establish). If an applicator in a State is certified as a commercial applicator under subsection (a) of section 4 before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d), the applicator must be recertified within two years after the date the training programs of the State comply with the minimum standards of the Administrator, or within an earlier time as the State may prescribe. The requirements of subsection (d) for registered commercial applicators would take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (e): Except as provided below, the provisions of new subsection (e) would take effect in a State on the expiration of the compliance period prescribed by subsection (h). If an applicator in a State is certified as a private applicator under subsection (a) before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (e), the applicator must be recertified within two years after the date the training programs of the State comply with the minimum standards of the Administrator, or within an earlier time as the State could prescribe. The requirements of subsection (e) for supervised private applicators would take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (j): The requirements of new subsection (j) regarding enforcement officer training would take effect one year after the Administrator issues the training materials specified in new subsection (g).

Section 601(c) would amend section 8 of the Act (records) to add new subsections (c) through (f).

New subsection (c) provides rules regarding applicator records. It provides that the Administrator must require each commercial applicator to maintain records of pesticide applications, including the identity and amount of the pesticides applied and the date and location of the applications, for a period of two years after each application. No regulations prescribed by the Administrator under the Act could require any private applicator to maintain any records or file any reports or other documents.

New subsection (d) deals with pesticide dealer records. It provides that the Administrator, by regulation, must require each pesticide

dealer to maintain a record of each sale or distribution of (1) a pesticide classified for restricted use and (2) any other pesticide designated by the Administrator by regulation because it may cause significant adverse effects on health or the environment. The records must include the identity of the pesticide sold, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer must maintain the records for three years after the date of the distribution or sale.

New subsection (e) deals with access to records and enforcement findings. It provides that any pesticide dealer or commercial applicator must afford, to any employee or former employee of the dealer or applicator, access to records required to be kept under new subsections (c) and (d) that directly relate to the employee's employment duties. Each pesticide dealer or commercial applicator must afford to any customer of the dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by the applicator at the request of the customer or under a contract with a customer.

Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, must make available reports of the findings of the investigation or action to the complainant. On the request of a complainant, the agency must provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action. The records for which access is provided must be accessible within 30 days after the public health or in a medical emergency, the records must be provided as soon as possible, but no later than 24 hours after the request is made.

A copy of any record required to be maintained under subsections (c) or (d) must be submitted, on request, to a State agency with primary enforcement responsibility under section 26 of the Act.

Under new subsection (f), an employer who uses or supervises the use of a pesticide must know or have access to the brand name and common or chemical name of the pesticide, and know or have access to the safety, first aid, and antidote information listed on the labeling of the pesticide, and must be responsible for promptly making the information available, on request, to any employee exposed to a pesticide and to treating medical personnel.

Section 601(c) would repeal section 11 of the Act (standards applicable to pesticide applicators) to conform with the amendments made to section 8 of the Act, as described above.

Section 601(d) would amend section 12 of the Act (unlawful acts) to make it a violation of the Act to obtain and use records acquired under new subsection (e) of section 8 (to be added by section 601(c) of the bill) in furtherance of a commercial purpose.

TITLE VII—DATA COMPENSATION

Section 701—Defensive data

Section 701 would rewrite clause (ii) of section 3(c)(2)(B) of the Act relating to the joint development of additional data to support existing registrations of pesticides by two or more registrants. As rewritten, clause (ii) will have four subclauses.

Under current law, each registrant of a pesticide for which additional data are needed to support the registration must provide evidence, within 90 days after receipt of notification by the Administrator that the additional data are needed, that it is taking appropriate steps to secure the data. This provision will be included in new clause (ii) as subclause (I).

The second and third sentences of clause (ii) currently provide that two or more registrants may agree to develop jointly, or share in the cost of developing, such data if they agree and advise the Administrator within 90 days after notification; and that a registrant who agrees to share in the cost of data is entitled to examine and rely on the data in support of the registration. This provision, except as modified by new subclause (II), will be included in new subclause (III).

New subclause (II) adds, to clause (ii), a new requirement that each registrant of a pesticide that contains an active ingredient that is only used for application in the production of food, feed, or fiber *must* agree—by the ninetieth day after notification—to develop jointly, or share in the cost of, the required additional data. They must advise the Administrator of their intent by the ninetieth day after notification. Any registrant under such agreement will be entitled to examine and rely upon the data in support of maintenance of the registration.

New subclause (IV) provides that, if a pesticide contains active ingredients used for application on food, feed, or fiber *and* for other purposes, the registrants of the pesticide who are subject to a requirement to submit additional data will be subject to subclause (II) or (III), whichever the majority of the registrants of that pesticide agree to.

Section 701 also would amend the provision of clause (iv) of section 3(c)(2)(B), which currently provides that the Administrator may issue a notice of intent to suspend a registrant's registration involved in the data call-in if the registrant has failed to (1) take appropriate steps to secure the required data, (2) failed to participate in a procedure for reaching agreement concerning a joint data development arrangement or in an arbitration proceeding under section 3(c)(2)(B), or (3) failed to comply with the terms of an agreement or arbitration decision concerning such an arrangement.

Under the amendment, the Administrator would be given similar authority to issue a notice of intent to suspend if the Administrator determines a registrant has failed to take the mandatory data development or cost-sharing action to be required by new subclause (II) of clause (ii).

The amendments made by section 701 would take effect with respect to notices issued under seciton 3(c)(2)(B) after the effective date of the bill.

Section 702—Data compensation and arbitration

Section 702(a) would amend clause (ii) of section 3(c)(1)(D) relating to the compensation of original data submitters. It would amend clause (ii) of section 3(c)(1)(D) to designate the current provisions as subclause (I) and add new subclauses (II) and (III) analyzed below.

Under current law (to be redesignated as subclause I), the pertinent provisions of clause (ii) provide that, subject to the exlcusive use provisions of clause (i), with respect to data submitted after December 31, 1969, to support applications under the Act, existing registrations, and registration, the Administrator can consider the data (without the permission of the original data submitter) in support of an application by any other person (the "applicant") within the 15-year period after the data were submitted only if the applicant makes an offer to compensate the original data submitter. The terms and amount of compensation are to be fixed by agreement between the original data submitter and the applicant or, failing agreement, *binding* arbitration as provided for in clause (ii). Either party can initiate the binding arbitration proceeidngs if they cannot reach agreement on the terms and amount of compensation within 90 days after the applicant's offer to compensate is delivered to the data submitter. The parties to the arbitration must share equally in the fees and expenses of the arbitrator.

The new provisions of subclause (II) provide that, if the term of a patent for a registered pesticide is extended after the date of enactment of the bill under an Act of Congress that amends title 35 of the United States Code to authorize an extension of the term of an unexpired patent irrespective of the date the pesticide underwent its regulatory review period, the amount of compensation to be paid under arbitration under new subclause (I) for the use of data would be a fair share of the cost of producing the data plus a value premium not to exceed that share, as determined in the arbitration process. The bill does not address the issue of amount of compensation in other cases, that do not come under new clause (II).

New subclause (III) would apply to data compensation cases involving pesticides with expired patents. For any such pesticide, the terms and amount of compensation for data submitted for such pesticide, to be paid by a person who intends to file an application for registration that would cite such data, could be fixed before the application for registration is filed, by arbitration under new subclause (I) initiated by the person seeking to use the data. The arbitration award would be binding on the original data sumitter, but nonbinding on the prospective applicant until he submits his application. Then, the arbitration award would be binding on him also. Each party to the first arbitration under new subclause (III) on a particular set of data would share equally in the fees and expenses of the arbitrators and pay its own attorney's fees. In any subsequent arbitration under subclause (III) (providing for partially nonbinding arbitration) on those data, the party seeking to use the data would have to pay the fees and expenses of the arbitrators, its own attorney's fees, and the attorney's fees for the original data submitter. The provisions of subclause (I) not in conflict with the

special rules of subclause (III) would apply to arbitrations under subclause (III).

TITLE VIII—MISCELLANEOUS PROVISIONS

Section 801—State registrations

Section 801 would amend section 24(c) of the Act to require that, when a State provides a registration for additional uses of a Federally registered pesticide to meet special local needs, the registration will expire and be of no further effect (without further action by the Administrator) (1) at the end of the period, if any, provided as the duration of the registration by the State that approved it, or (2) ten days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.

Section 801 would further amend section 24(c) to add a new provision requiring the Administrator to establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use. (NOTE: Under current law, the Administrator has authority, with limits, to disapprove any State special local needs registration during the first 90 days it is in effect).

Section 802—Definitions

Section 802(a) would amend section 2(bb) of the Act to clarify the term defined therein—"unreasonable risk to man or the environment". As currently defined, the term means any unreasonable risk to man, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. The amendment would add a new provision to section 2(bb) clarifying that, as used in the definition, the word "man" includes unborn human beings from the moment of conception.

Section 802(a) also would amend section 2(ee) of the Act to provide that the term defined therein—"to use any registered pesticide in a manner inconsistent with its labeling"—does not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling (unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency); or (2) employing any method of application not prohibited by the labeling (unless the labeling specifically states that the product may be applied only by the methods specified on the labeling). The words in parentheses are those that would be added to current law by the amendment.

Section 802(a) also would amend section 2 of the Act by adding a new subsection (kk) to define the term "to distribute or sell". Under the new definition, the term means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticide products or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

Section 802(b) would make conforming amendments to sections 3(a) and 12(a) of the Act, which currently use essentially the same language as that of new subsection (kk) of section 2, to be added by section 802(b). The amendments would substitute for such language the term defined in subsection (kk)—"distribute or sell".

Section 802(b) would further amend section 12(a) (unlawful acts) to add to the current prohibition under paragraph (2)(F) of section 12(a)—against the use of a restricted use pesticide for purposes not in accord with the Act and its regulations—a prohibition against the distribution or sale (as that term would be defined under new subsection (kk) of section 2) for such purposes.

Section 803—Information requested

Section 803 would amend section 7 of the Act to add a new subsection (f) to require the Administrator, consistent with section 3507(a)(1) of title 44 of the United States Code (public information collection activities), to catalogue and retrieve data in a manner to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data.

Section 804—Cooperative agreements

Section 804 would rewrite and make technical modifications to subsection (c) of section 23 of the Act. As rewritten, subsection (c) would authorize the Administrator to enter into cooperative agreements and grants with States and Indian tribes to—

(1) delegate to any State or Indian tribe the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, train personnel of the State or Indian tribe to cooperate in the enforcement of the Act, and assist States and Indian tribes in implementing cooperative enforcement programs through grants;

(2) provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as agreed under the cooperative agreements, of conducting training programs for the certification of applicators. Funds would be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator; and

(3) provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under the cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State certification plan approved under section 4(a) of the Act. Funds would be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

There would be authorized to be appropriated such sums as may be necessary for cooperative agreements under the subsection.

Section 805—Scientific advisory panel

Section 805 would amend section 25(d) of the Act to expand the FIFRA scientific advisory panel from 7 members to 9 members, and make the panel permanent.

Section 806—Authority for EPA action

Section 806 would amend the second sentence in subsection (a) of section 27 of the Act.

While section 26 of the Act provides for the States to have primary enforcement responsibility with respect to pesticide use violations, section 27 of the Act contains provisions for Federal action on violations when a State fails to ensure enforcement of pesticide use rules.

The second sentence in subsection (a) of section 27 currently provides that the Administrator can act on a pesticide use complaint or information if the State does not commence appropriate enforcement action on the case within 30 days after receiving the complaint or information. As rewritten, the second sentence would provide authority for the Administrator to act on a complaint or information if a State does not promptly initiate appropriate investigative action after receiving a referral from the Administrator or does not initiate appropriate enforcement action within 90 days after receipt of the referral.

Section 807—Expiration of State primary enforcement responsibility

Section 807 would amend section 26 of the Act by adding a new subsection (d) to provide that the primary enforcement responsibility of a State under the Act with respect to pesticide use violations will expire on January 1, 1989, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14 of the Act.

Section 808—Unlawful acts

Section 808(a) would amend subsection (a) of section 12 of the Act, which describes the acts that are prohibited under the Act. Paragraph (1)(A) of subsection (a) (which currently provides that it is unlawful to distribute or sell pesticides that are not registered except as provided in section 6(a)(1) of the Act (disposal of existing stocks)) would be technically rewritten to provide that it will be unlawful to distribute or sell any pesticide that is not registered under section 3 of the Act or whose registration has been cancelled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under the Act.

Similarly, section 808(a) would technically revise paragraph (2)(B) of subsection (a) to conform to the changes to be made in sections 8 and 9 of the Act by title IV of the bill. Under paragraph (2)(B), as rewritten, it would be unlawful for any person to refuse to—

(1) prepare, maintain, or submit any records required by or under the Act;

(2) submit any reports required by or under the Act; or

(3) allow any entry, inspection, copying of records, or sampling authorized by the Act.

Section 808(a) would—

(1) revise the prohibition in paragraph (2)(J) of subsection (a) against violations of suspension orders under section 6 to add references to suspension orders under sections 3(c)(2)(B) and new 3A (to be added to the Act by section 105(a) of the bill); and

(2) revise paragraph (2)(K) of subsection (a) (which currently prohibits violations of "any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1)") so that it would prohibit violations of "any cancellation order issued under this Act"; and

(3) with respect to the prohibition against falsification of records under paragraph (2)(M) of subsection (a), change a reference to records maintained "under section 8" to records maintained "under this Act".

Section 808(a) also would add new subparagraphs (R), (S), and (T) to paragraph (1) of subsection (a) to add three new prohibitions, as follows:

(1) To willfully falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, and submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by the Act.

(2) To willfully submit data known to be false to the Administrator in support of a registration.

(3) To violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25(f) of the Act.

Section 3(a), as amended by sections 802(b) and 901(a) of the bill, will authorize the Administrator to regulate the sale, distribution, and use of unregistered pesticides. Section 19(a) establishes procedures for the disposal and transportation of pesticides. Section 25(c)(3) authorizes the Administrator to establish pesticide packaging standards. Section 25(f), to be added by section 815, will provide for a worker health and safety program.

Section 808(b) would amend section 12 of the Act by adding a new subsection (d) to provide that, when construing and enforcing the provisions of the Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person will be deemed to be the act, ommission, or failure of the employer as well as that of the person employed.

This provision currently is found in paragraph (4) of section 14(b) of the Act. Section 808(b) would repeal paragraph (4) of section 14(b) to reflect the placement of the provisions in section 12.

Section 809—Penalties.

Section 809(a) would amend subsection (a) of section 14 of the Act, which provides civil penalties for violations of the Act. The amendment would revise paragraphs (1) and (2) of subsection (a) to increase penalties, provide penalties for subsequent violations, and conform subsection (a) to other changes to the Act to be made by the bill.

As revised, paragraphs (1) and (2) will provide that—

(1) any registrant, applicant for a registration, or pesticide testing facility that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If the registrant, applicant for a registration, or pesticide testing facility violates a provision of the

Act after having violated the same or similar provision of the Act, the Administrator may assess a civil penalty of not more than $50,000 for each subsequent violation (new paragraph (1));

(2) any commercial applicator of restricted use pesticides, or any other person (not including a registrant, applicant for a registration, or pesticide testing facility) who distributes or sells pesticides or devices that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator could assess a civil penalty of not more than $20,000 for the subsequent violation (new paragraph (1)); and

(3) any private applicator who violates any provision of the Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation and any other person not described in item (1) or (2) above that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator could assess a civil penalty of not more than $2,000 for the subsequent violation (new paragraph (2)).

Section 809(a) also would add a new provision to paragraph (2) to authorize the Administrator to waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment. (NOTE: A provision currently in paragraph (2) specifically applicable to pest control operations would be deleted by section 809(a).)

Section 809(a) would amend paragraph (3) of section 14(a), regarding hearings to assess civil penalties, to provide that if a person neither resides nor has its principal place of business in the United States, the Administrator could designate a site for the hearing in the United States that is reasonably convenient for the parties.

Section 809(a) would amend paragraph (4) of section 14(a) to require the administrator, in determining the amount of a civil penalty, to consider the economic benefit (if any) gained by the violation of the Act.

Section 809(b) would amend paragraph (1) of section 14(b) of the Act, which provides criminal penalties for violations of the Act by persons (except private applicators) in the pesticide industry. The amendment would increase some penalties and conform paragraph (1) to other changes in the Act made by the bill.

As revised, paragraph (1) would provide that any registrant, producer, or pesticide testing facility that knowingly violates any provision of the Act will be fined not more than $50,000 or imprisoned for not more than one year, or both. Any commercial applicator of a restricted use pesticide, or other any person (not including a registrant, producer, or pesticide testing facility) who distributes or sells pesticides or devices that knowingly violates any provision of the Act will be fined not more than $25,000 or imprisoned for not more than one year, or both.

Section 809(b) also would amend paragraph (2) of section 14(b) of the Act to increase the maximum penalty for the knowing violation of the Act by a private applicator or other person not covered by paragraph (1) from $1,000 to $2,000, and increase the possible term of imprisonment from 30 days to 60 days.

Section 809(c) would amend section 14(a) of the Act by adding a new paragraph (6) to authorize the Administrator, in connection with administrative proceedings under the civil penalties provisions of the Act, to issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and to request the Attorney General to bring an action to enforce a subpoena. The district courts of the United States would have jurisdiction to enforce the subpoenas and impose sanctions.

Section 810—Congressional review

Section 810 would rewrite paragraph (4) of section 25(a) of the Act, which provides for review by Congress of rules and regulations issued under the Act. Current provisions, which provide for congressional veto of rules and regulations, would be deleted. As rewritten, paragraph (4) will provide that the Administrator, simultaneously with the promulgation of any rule or regulation under the Act, must transmit a copy to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation would not become effective until 60 calendar days after the rule or regulation is transmitted.

Section 811—Review of regulations

Section 813 would amend section 16 of the Act (administrative procedure and judicial review) by adding a new subsection (e) to prescribe the exclusive procedures for the review of regulations issued under the Act.

Paragraph (1) of new subsection (e) provides that any regulation issued under the Act and first published in the Federal Register in final form after the effective date of the bill or any refusal of a petition to modify or rescind a regulation issued under the Act will be reviewable only as provided in subsection (e). Any person could obtain judicial review of the regulation or the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a regulation must be filed within 120 days after the date of promulgation of the regulation as determined by the Administrator in the Federal Register. Any such petition for review of a refusal to modify or rescind a regulation must be filed within 120 days after the refusal. In either case, the scope of review would be as specified in section 706 of title 5, United States Code. Section 706 of title 5 provides that

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

The commencement of proceedings under subsection (e) would not, unless specifically ordered by the court to the contrary, operate as a stay of the regulation.

Under paragraph (2) of new subsection (e), a regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under the Act would not be subject to judicial review (1) in any suspension, cancellation, or denial proceeding under the Act or in any appeal therefrom, or (2) in proceedings or appeals under section 13 (stop sale, use, removal, and seizure) or 16 (penalties) of the Act, or under subsection (c) of section (b) (district court actions to enforce and to restrain violations of the Act), except on request of an agricultural producer who is adversely affected by the action.

Under paragraph (3) of new subsection (e), if a person who is a party to a proceeding described above that is based on a regulation issued under the Act petitions the Administrator to modify or rescind the regulation, the application of the regulation in the proceeding must be stayed until the Administrator issues a final decision on the petition.

Paragraph (4) of new subsection (e) defines the term "agricultural producer", as used in subsection (e), to mean a nongovernmental producer of agricultural commodities who (1) uses or supervises the use of any pesticide for the production of such commodities on property he or his employer owns or rents, or (2) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the other person's land.

Section 812—Delegation and cooperation

Section 812 would amend section 22 of the Act (delegation and cooperation) by adding a new subsection (c) to provide that the Administrator, in exercising any authority under the Act, will not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority

to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that the exercise of authority by the Administrator under the Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1). To ensure the safety and health of workers, the Administrator and the Secretary of Labor must seek to reach agreements and to coordinate the exercise of their statutory authority.

Section 4(b)(1) provides that provisions of the Occupational Safety and Health Act do not apply to working conditions of employees with respect to which other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

The purpose of section 4(b)(1) is to prevent duplication of effort among Federal agencies charged with the protection of workers' safety and health. New subsection (c) would retain the principle of 4(b)(1) while making it clear that the Department of Labor and the Environmental Protection Agency should enter into agreements to clarify their respective exercise of statutory authority.

It is the intent of the Committee that the courts give deference to such agreements. As an example, EPA might be in the best position to advise applicators on the proper handling of a pesticide, while the Department of Labor might be better able to establish safeguards for other workers. When this is the case, and when the agencies can reach an agreement, new subsection (c) would give explicit statutory authority for such an agreement.

Section 813—Indemnity report by EPA

Section 813 would amend section 15 of the Act (indemnities) by adding a new subsection (c) to require the Administrator, if he has taken an action that requires the payment of indemnification, to report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate—

(1) the action taken that requires the payment of indemnification;

(2) the reasons for taking the action;

(3) the estimated cost of the payment;

(4) the effect the payment would have on the budget of the Administrator to implement the Act without a specific additional appropriation for the payment; and

(5) a request for the appropriation of funds for the payment.

Section 841—Groundwater authority

Section 814 would amend the Act by adding a new section 32 relating to groundwater. Subsection (a) of new section 32 would require the Administrator, as appropriate and necessary, to use the authorities under the Act of provide for the protection of drinking water and groundwater against contamination by pesticides.

Subsection (b) of new section 32 would require the Administrator to use maximum contaminant levels established under title XIV of the Public Health Service Act, whenever available, as groundwater

residue guidance levels for the purposes of carrying out subsection (a).

Subsection (c) of new section 32 would require the Administrator, in carrying out subsection (a), to consult with, and take into account the views of, the States on—

(1) the distinction between drinking water, shallow groundwater that is not a potential source of drinking water, and groundwater that is a potential source of drinking water,

(2) degradation of pesticides in groundwater, and

(3) appropriate means for responding to and preventing pesticide contamination of drinking water and groundwater.

Subsection (d) of new section 32 provides that, in carrying out subsections (a) and (c), the Administrator must consult with the Secretary of Agriculture.

Section 815—Worker health and safety

Section 815(a) would amend section 25 of the Act (authority of the Administrator) by adding a new subsection (f) relating to worker health and safety

Paragraph (1) of new subsection (f) would require the Administrator, as soon as practicable, to promulgate regulations that require the protection, as appropriate and necessary, of (1) *Employees who mix, load, or apply pesticides* and (2) *agricultural employees who work in pesticide-treated areas.* The administrator must promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement established by the Administrator would not apply to any person who is required to receive the training under new subsections (d) and (e) of section 4 of the Act (to be added by section 601(b) of the bill). The term "employees", as used in paragraph (1), would not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

Under paragraph (2) of new subsection (f), the Administrator must promulgate the regulations that require the protection, as appropriate and necessary, of employees (other than *agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas*) not later than three years after the date of enactment of the bill.

The Administrator must provide six months for comments on the proposed regulations to be issued under paragraph (1) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas, and promulgate these regulations not later than two years after the date of enactment of the bill.

Paragraph (3) of new subsection (f) provides that, not later than six months after the date of the publication of the notice of proposed rulemaking issued for the regulations (described in the preceding paragraph) on agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas, the Secretary of Agriculture must submit to the Administrator a report on the impact, cost, and effectiveness of the regulations on the agricultural community, and submit a copy of the report to Congress.

Paragraph (4) of new subsection (g) would require the Administrator to transmit, simultaneously with promulgation, a copy of the

regulations issued under paragraph (1) to the Secretary of the Senate and the Clerk of the House of Representatives. The regulations would not become effective until 120 days after the date the regulations are transmitted. (NOTE: It would be an unlawful act to violate these regulations under section 12 of the Act, as amended by section 808(a) of the bill.

New subsection (g) will create a mandatory duty for the Administrator to issue regulations to (1) protect employees who mix, load, and apply pesticides and agricultural employees who work in pesticide-treated areas, and (2) train employees who mix, load, and apply pesticides. The content and scope of such regulations will be determined by the Administrator as deemed appropriate and necessary. One intent of this subsection is to provide statutory direction to the Environmental Protection Agency to proceed with its current efforts to issue farmworker regulations. This subsection is not intended to alter the content or scope of the farmworker regulations under review by EPA.

The EPA must continue to develop and maintain expertise on working conditions and practices of workers exposed to pesticides and use this expertise for such activities as evaluating registration, reregistration, public interim administrative review, and cancellation decisions with respect to effects of such actions on worker health and safety.

Section 816—Authorization for appropriations

Section 816 would amend section 33 of the Act (as redesignated by section 202(b) of the bill), effective October 1, 1986, to authorize to be appropriated to carry out the Act (other than sections 23(a) and 31) $78,363,500 for fiscal year 1987, of which not more than $13,735,500 must be available for research under the Act, $87,414,200 for fiscal year 1988, of which not more than $14,343,600 must be available for research under the Act, $91,673,400 for fiscal year 1989, of which not more than $14,978,200 must be available for research under the Act, $98,305,800 for fiscal year 1990, of which not more than $15,625,900 must be available for research under the Act, and $106,808,700 for fiscal year 1991, of which not more than $16,300,100 must be available for research under the Act.

SUBTITLE B—OTHER PROVISIONS

Section 821—Liability

Section 821 provides that—

(1) an agricultural producer will not be liable in any action brought after the effective date of the bill, under any Federal statute, for damages caused by pesticide use unless the producer has acted negligently, recklessly, or intentionally. Proof that an agricultural producer used a pesticide consistent with label instructions will create a rebuttable presumption that the agricultural producer did not act negligently;

(2) an agricultural producer will not be held liable in an action brought under section 14 of the Act (penalties) for civil penalties for a violation of section 12(a)(2)(G) of the Act (which prohibits persons from using registered pesticides in a manner

inconsistent with the labeling) unless the producer used a pesticide in a manner inconsistent with its labeling. Proof that a pesticide was used in a manner consistent with its label instructions will create a rebuttable presumption that the agricultural producer did not violate section 12(a)(2)(G) of the Act. The first provision described above, which serves to introduce the second provision described above, merely restates the effect of current law; and

(3) for the purposes of these provisions, the term "agricultural producer" means a nongovernmental producer of agricultural commodities who uses or supervises the use of any pesticide for the production of the commodities on property owned or rented by him or his employer, or who without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the other producer's land.

Nothing in section 821, in any way, implies a private cause of action under the Act.

Section 822—Evaluation by the Comptroller General

Section 822 would require the Comptroller General of the United States to conduct an evaluation of the programs and activities authorized by the amendments to the Act made by the bill and make a final report to Congress on his evaluation no later than December 31, 1988. The Comptroller General must include in the evaluation the effect that the Act, as amended by the bill, is having on the cost and availability of pesticides to farmers as well as other producers of food and fiber. The evaluation must include an analysis of the reregistration program under the Act and any program conducted by the Administrator under the Act relating to groundwater.

For purposes of conducting the program evaluations, the Comptroller General, or his duly authorized representative, would have access to and the right to examine all recorded information within the possession or control of the Administrator or within the possession or control of pesticide registrants subject to regulation under the Act. The Comptroller General or his representative would be subject to the same restrictions regarding the disclosure of trade secret information as are the employees of the Environmental Protection Agency.

Section 823—IR-4 program

Section 823 would amend section 2(c) of the Act of August 4, 1965, relating to agricultural research grants, to require the Secretary of Agriculture to provide support under such Act for the interregional project number 4 program (commonly referred to as the "IR-4 program"), which generates health and safety data on minor use pesticides that are used for agricultural purposes.

Section 824—Pesticide risk rating

Section 824 would require the Administrator to contract with the Board of Agriculture of the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricul-

tural commodities. The risk rating must take into consideration methods of application, chronic and acute toxicity, and anticipated losses to and persistence in the environment. In conducting the study, the National Academy of Sciences must seek information and advice from recognized public and private sector scientists and provide opportunity for public comment on the preliminary findings relating to the development of a risk rating.

The National Academy of Sciences must report the findings of the study to the Administrator and to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate within 18 months after the date of the enactment of the bill. The risk rating study must be conducted at the cost established by the Administrator, in consultation with the National Academy of Sciences. The authority of the Administrator to enter into contracts under section 824 would be effective only to such extent or in amounts as are provided in advance in appropriation Acts.

Section 825—Study of nonagricultural pesticides

Section 825 would require the Administrator to study and report to Congress within one year after the date of the enactment of the bill on pesticide volume, use sites, and target insects for nonagricultural pesticides.

Section 826—Dioxin study

Section 826 would require the Administrator to conduct a study under which samples of human breast milk would be analyzed for residues of isomers of chlorinated dioxins and dibenzofurans. The Administrator must report to Congress the findings from the analysis of the samples not later than 2 years after the date of enactment of the bill.

Section 827—Pesticide drift

Section 827 would require the Administrator, within 2 years after the date of enactment of the bill, to report to the Committee on Agriculture of the House of Representatives and to the Committee on Agriculture, Nutrition, and Forestry of the Senate on the incidence and potential adverse effects on human health and the environment of the drift of pesticides from the site of application at the time of application.

Section 828—Survey of naturally occurring agents that act as pesticides

Section 828 would require the Administrator to conduct a survey to determine what research has been, or is being, conducted to establish the extent to which agents that act as pesticides are manufactured by plants and thereby exist naturally in fruits, vegetables, grains, legumes, and oilseeds commonly consumed by persons in the United States. The Administrator must provide a report on the findings of the survey to the Committee on Agriculture of the House of Representatives and to the Committee on Agriculture, Nutrition, and Forestry of the Senate not later than December 31, 1987, and release the findings to the public. The report must include information on the extent to which the naturally occurring

agents have been identified, on the nature of the agents, and on the extent to which the agents have been shown to be toxic, carcinogenic, or mutagenic.

TITLE IX—CLARIFYING AND TECHNICAL AMENDMENTS

Section 901—Clarifying amendments

Section 901(a)(1) would add a new provision to subsection (a) of section 3 of the Act, which contains one sentence to be revised by section 802(b) of the bill to prohibit the distribution or sale of an unregistered pesticide (current law has essentially the same provision). The added provision provides that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under the Act and that is not the subject of an experimental use permit or an emergency exemption.

Section 901(a)(2) would amend section 3(d) of the Act to clarify that pesticides may be reclassified by regulations, and to clarify the Administrator's authority to regulate the use of restricted pesticides.

Section 901(a)(3) would amend section 3(c)(7)(A) of the Act to clarify that an applicant seeking conditional or amended registration may cite as well as submit required data.

Section 901(b) would amend section 4 of the Act (certified applicators) to clarify the Administrator's authority to issue regulations under that section of the Act.

Section 901(c) would amend section 7(c) of the Act (registration of pesticide production or distribution establishments) to clarify the Administrator's authority to issue regulations describing information and reports to be supplied under section 7 of the Act.

Section 901(d) would amend section 25(c) of the Act (specified authorities of the Administrator) to clarify that the Administrator may issue regulations to carry out the authority provided in that section of the Act.

Section 902—Technical amendments

Section 902 would make clerical, conforming, and other technical amendments to the Act.

Section 903—Table of contents amendments

Section 903 would make amendments to the table of contents of the Act to conform with the amendments to the Act made by the bill.

TITLE X—EFFECTIVE DATE

Section 1001—Effective date

Section 1001 provides that, except as where otherwise specified by the bill, the amendments to the Act made by the bill will take effect on the expiration of 60 days after after the date of enactment of the bill.

COMMITTEE CONSIDERATION

HEARINGS

The Subcommittee on Department Operations, Research, and Foreign Agriculture held two days of hearings on March 19 and 20, 1986, to consider and review proposed changes and amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). During these hearings, testimony was received from various witnesses representing agricultural producers, manufacturers of agricultural chemicals, consumer and environmental groups, Federal and State regulatory officials, and others affected by the manufacture, distribution, and use of pesticide products. Comments were received on a variety of bills introduced during the 99th Congress as amendments to FIFRA, including H.R. 2482, H.R. 4364, H.R. 4440, and H.R. 4513.

I

On March 19, 1986, the Subcommittee met to receive testimony about proposed FIFRA amendments, including H.R. 4364. This bill represented an agreement between organizations representing 92 agricultural chemical companies and 43 consumer, environmental, and labor groups.

The first panel was comprised of representatives of agricultural chemical manufacturers, and the second panel was comprised of representatives of consumer and environmental groups that had drafted the agreement. These witnesses presented and explained their agreement to members of the Subcommittee, and took questions from members about the bill's potential impact on agricultural producers and its design for achieving improved protection of health and the environment, especially through the accelerated development of health and safety data about agricultural chemicals.

The third panel included representatives of other groups who primarily produce or use nonagricultural pesticides such as those used for structural pest control or antimicrobial purposes. These witnesses were especially concerned about the effect of registration fees on smaller firms who manufacture and register low-volume active ingredients, as well as about the training, supervision, and liability of those who apply structural-use pesticides. Members' question dealt extensively with the trade-off between appropriate registration fees and the need to provide adequate funds to implement the provisions of the bill. Questions also centered on the desirability of more and better training for all pesticide applicators while not unduly burdening producers who need to routinely use these chemicals.

The fourth panel of the day included witnesses from the American Farm Bureau Federation and other grower groups that use pesticides in agricultural operations, as well as a representative of the Texas Department of Agriculture. They generally supported the goals and design of H.R. 4364, but voiced concern over the potential impact of registration fees that would, in their view, inevitably be passed along to agricultural producers. Their concern was that while the fees in the proposed amendments were perhaps modest, the Federal Government might seek far higher fees in the

future related to the regulation of pesticide use, and that these would also be passed along to the detriment of U.S. agricultural producers. Members questioned them about these views, and generally agreed that any fees imposed by legislation should be considered earmarked revenue to help complete the reregistration process, and that the Subcommittee would look unfavorably on proposals for additional revenues to be raised through registration fees or other means.

The last panel of the day included witnesses from other environmental and labor groups who generally supported the provisions of H.R. 4364, and wanted to suggest other changes to FIFRA. Specifically, representatives of labor groups were especially critical of EPA's past efforts to protect agricultural workers from some of the hazards of pesticide use, and expressed hope that the amendments would finally enhance EPA's efforts in this area. Representatives of the Audubon Society explained to the members why they believed provisions allowing for greater public participation in registration decisions, not included in H.R. 4364, should be added. Members asked these witnesses to elaborate more fully on their views and why they believed such additional changes were desirable.

II

On March 20, 1986, the Subcommittee met for the second day of hearings about proposed FIFRA amendments. The first witness was Assistant Administrator of the Environmental Protection Agency, Dr. John Moore, who testified about the desirability of the proposals in H.R. 4364 from the agency's perspective. While generally supportive of the provisions of the bill because many of its apparent changes were already being implemented by EPA under existing authority, Dr. Moore did express concern about the adequacy of revenues raised by the bill to support activities required under it, and was opposed to the proposal for the review of inert ingredients of pesticide formulations contained in H.R. 4364. Members asked extensive questions about the adequacy of allocated budget funds as well as those revenues called for in the bill to cover the requirements the bill would place on EPA. Also pursued was the precise way that EPA envisioned inert ingredient data and review requirements, since EPA viewed the proposed amendments as unworkable. Members agreed that the general goal was to continue the recent progress EPA had made on the inert ingredient issue, and promised to consider changes during markup that would both preserve the direction of current EPA efforts while not unduly burdening the agency.

The second witness was a representative of the U.S. Department of Agriculture, who did not have extensive comments about the proposals. While generally supportive, this witness asked for continued coordination between the Department of Agriculture and EPA in matters regarding the use and regulation of pesticide products.

The first panel of witnesses for the day included representatives of groups and individuals who had an interest in the effects of pesticides when misused and unexpected effects of pesticides. Detailing incidents of misuse and unexpected contamination, these witnesses

expressed the hope that the FIFRA amendments would result in less frequent such episodes in the future. Members questioned the witnesses about how these incidents might be prevented with the proposed amendments, especially the provisions for greater training and supervision of those who commercially apply pesticides.

The second panel of witnesses included representatives of firms and organizations with an interest in the data compensation provisions of the current FIFRA and as proposed in H.R. 4440. The witnesses sharply disagreed about the impact of current provisions on innovation trends and retail costs of pesticide products. Members extensively questioned the witnesses in order to better understand the arguments for and against changes in current compensation provisions. The members also gave a strong directive to the witnesses that their respective organizations should attempt to resolve their differences before further Committee consideration of any proposal in order to prevent such a potentially divisive issue from hindering the legislative progress of the other proposed FIFRA amendments.

The last panel of witnesses included representatives of a trade association of firms that manufacture antimicrobial pesticide products, and an organization promoting alternatives to the use of live animals in toxicity tests.

The first witness detailed an example of how certain antimicrobial manufacturers might be unable to afford the active ingredient reregistration fees required by H.R. 4364.

The second witness encouraged the Subcommittee to insist on further progress by EPA to reduce the use of live test animals. Following is a copy of a letter from the Environmental Protection Agency, dated July 16, 1987, regarding their policy on the testing of live animals.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, DC, July 16, 1986.

Hon. BERKLEY BEDELL,
Chairman, Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: This is in response to a number of questions you have received regarding the policy of the Environmental Protection Agency (EPA) on the LD_{50} test.

EPA's acute toxicity testing guidelines clearly state that we discourage the use of the "classic LD_{50} test" which uses large numbers of animals. We also stress specific ways of reducing the use and numbers of animals. We go beyond simple statements of intent and include a testing philosophy and methods that can be used to develop useful data. The guidelines emphasize using data from structurally related chemicals when possible to make preliminary judgments about chemical safety. They incorporate the use of a "limit test" using 10 or fewer test animals, which itself may be sufficient to yield information on acute toxicity.

We believe our testing guidelines offer scientifically sound guidance for determining human safety while using as few test animals as possible. EPA is committed firmly to keeping track of research oriented toward developing alternatives to using animals in acute

toxicity evaluation. At the present time, these methods are still in early stages of development. As ways to further reduce the use of or replace animals in acute toxicity testing become accepted by the scientific community, EPA will modify its guidelines accordingly.

EPA has notified private sector testing laboratories of the Agency's quidelines and our policy of discouraging the use of the "classic LD_{50} test." In addition, the Agency has notified the Organization for Economic Cooperation and Development (OECD) of its position and is working with the OECD to develop international guidelines for acute toxicity testing that reflect the use of fewer animals.

I am enclosing a copy of the EPA's LD_{50} fact sheet for your information. This should assist your staff in responding to the numerous questions you have received on this issue.

Sincerely yours,

JOHN A. MOORE,
Assistant Administrator for
Pesticides and Toxic Substances.

Attachment.

FACT SHEET

BACKGROUND ON ACUTE TOXICITY TESTING FOR CHEMICAL SAFETY

EPA's position on the LD_{50}

The Environmental Protection Agency (EPA) discourages the use of the "classic LD_{50}," which employs large numbers of animals in toxicity testing for chemical safety. We are aware that under certain circumstances there continues to be a need for the use of animals in acute toxicity testing for chemical safety. Where this need exists, the Agency recommends using the least number of animals necessary for the testing and in its acute toxicity test guidelines outline specific ways to reduce the use and numbers of animals.

Update of OPTS acute toxicity guidelines

The Agency wants the public and the commercial testing laboratories to understand fully its continuing commitment to using as few test animals as possible for acute toxicity testing. To this end, the Agency has revised its guidelines to reflect several approaches to determine acute toxicity. EPA recommends the following means to reduce the number of animals used to evaluate acute effects of chemical exposure while preserving its ability to make scientifically valid judgments about hazards.

Ways EPA is reducing the number of test animals for determining acute toxicity

Using data from structurally related chemicals.—The Agency encourages the review of existing acute toxicity information on chemical substances that are structurally-related to the agent under investigation. In certain cases one may be able to glean information from these surrogate chemicals to make preliminary safety judgments that aid in the interpretation of animal tests.

"Limit" test.—When acute lethality data are desirable. EPA's test guidelines encourage the use of methods that minimize the require-

ment for animals, sometimes by a factor of 90% as compared to the classic LD_{50} test. In the "limit" test, a single group of animals is given a large dose (5g/kg body weight) of the agent. If no lethality is demonstrated, no further testing for this information is pursued.

Estimation of lethal dose.—For those substances demonstrating lethality in a "limit" test, the Agency can use estimates of the dose associated with some level of lethality that are derived from abbreviated testing plans. With such an approach, use of greater numbers of animals or increased numbers of dose levels are not necessary.

Multiple endpoint testing.—The Agency stresses the simultaneous monitoring of several endpoints in animals in a single acute study including sublethal effects as well as lethality. Dosed animals are observed for abnormal behavioral manifestations such as increased salivation or muscular incoordination, in addition to the recovery from these effects during the observation period. Both dead and surviving animals are autopsied to evaluate internal evidence of organ toxicity. In some cases follow-up testing may be justified to pinpoint the kinds of abnormalities that have been found in the organs of the autopsied animals. This sound, scientific practice maximizes the data from a limited number of test animals.

Status of whole animal testing alternatives

Research continues on *in vitro* measures of acute toxicity testing as alternatives to whole animal testing. At the present time, none of these test systems are satisfactorily developed or validated. EPA believes that it must continue to rely on whole animal testing in order to obtain acute toxicity data. As soon as alternative methods are accepted by the scientific community, the Agency will encourage strongly their use.

October 1985.

Subcommittee Markup

The Subcommittee on Department Operations, Research, and Foreign Agriculture met on Wednesday, May 14, 1986, in business session to consider H.R. 4364, H.R. 4513, H.R. 2482, and H.R. 4440, bills pending before the Subcommittee to amend FIFRA. Mr. Bedell, Chairman of the Subcommitte, called the meeting to order and announced that a Committee Print prepared by staff would be used as the markup vehicle. The Committee Print contained amendments to FIFRA selected from among the pending bills and modified as a result of consultations among staff, representatives of the EPA, and other interested parties. After an explanation of the provisions of the Committee Print by staff, the Chairman announced that amendments would be in order.

Mr. Hatcher offered four amendments, to be considered en bloc. Mr. Hatcher explained that the first amendment would allow the Administrator to waive or reduce the fee for reregistration of pesticides regestered for minor uses, and antimicrobial pesticides that contain active ingredients for which production levels do not exceed 1,000,000 pounds per year. Mr. Hatcher explained that the second amendment would require the Administrator to exempt certain small businesses from the required reregistration fee. The

third amendment would provide for the apportionment of the fee among registrants according to their respective market share. The fourth amendment would provide a definition for the term "antimicrobial" and clarify that the term "pesticide" would include substances intended for use an antimicrobial. Mr. Bedell expressed concern that the definition of antimicrobial in the amendment would include a number of unintended products. Mr. Hatcher agreed to work with the staff to refine the definition. Mr. Bedell also expressed concern that the definition of a small business provided in the amendment might be too broad. After a discussion, Mr. Hatcher asked for unanimous consent to delete the small business fee exemption from the amendment. The Subcommittee agreed to the request without objection. The Subcommitte then agreed to the Hatcher amendment, as amended, by voice vote.

Mr. Roberts offered an amendment to delete the provisions in the Committee Print relating to the regulation of inert ingredients and substitute new provisions. Mr. Roberts explained that the provisions in the Committee Print would establish a rigid process that might slow down the inert ingredient review process of the EPA. Mr. Roberts said that the amendment would simply clarify the Administrator's existing authority to regulate inert ingredients in pesticides. Dr. John A. Moore, Assistant Administrator for Pesticide and Toxic Substances, EPA, was asked by Mr. Roberts for his comments. Dr. Moore responded that he considered the language in the Committee Print to be administratively cumbersome, while the proposed amendment would enable the agency to address the inerts issue without placing unnecessary burdens on the agency. Mr. Volkmer asked Dr. Moore if the agency presently could request health and safety data for inert ingredients from manufacturers under the Toxic Substances Control Act. Dr. Moore responded that has current interpretation of that Act is that exposure to inert ingredients in pesticides would probably not allow the agency to require testing, but if the inert has a large use in products other than pesticides, section 4 of that Act would allow the agency to require testing. Mr. Roberts commented that the purpose of his amendment would be to clarify that the EPA could require health and safety data on inert ingredients in pesticides under the FIFRA. The Subcommittee agreed without objection to a request by Chairman Bedell that the amendment be modified to allow the Administrator to use the Toxic Substances Act or FIFRA to require health and safety data. When asked by Mr. Gunderson, Dr. Moore explained the current EPA strategy on the regulation of inert ingredients. Mr. Volkmer expressed his concern that the amendment would not require the agency to proceed with its current plans to regulate inert ingredients. Mr. Roberts suggested that the Subcommittee adopt the amendment with the understanding that work would be done to refine the language to clarify that there is a commitment to the inerts program. Mr. Roberts suggested that the matter could be taken up again when the Full Committee considers the bill. Mr. Gunderson expressed his view that the language in the Committee Print would provide the Administrator with considerable discretion on how to regulate inerts. Mr. Bedell said he would agree to the adoption of the amendment with the understanding that additional language be worked out before full Com-

mittee markup to ensure that the agency moves ahead with the inerts program. The Subcommittee agreed, by voice vote, to the Roberts amendments, as modified.

Mr. Volkmer offered an amendment to specify that the word "man," in the term "unreasonable adverse effects on man or the environment" as used in FIFRA, be defined to include unborn human beings from the moment of conception. Mr. Volkmer explained that this amendment was adopted in a floor amendment to the FIFRA bill considered by the House of Representatives in 1982. The Subcommittee agreed, by voice vote, to the Volkmer amendment.

Mr. Brown offered an amendment to require the EPA to conduct a study on nonagricultural pesticides. Mr. Brown explained that the amendment resulted from the need for a better data base on the use of pesticides in urban areas. The study would fill certain gaps in previous EPA studies, Mr. Brown told the Subcommittee. The Subcommittee, by voice vote, agreed to the Brown amendment.

Mr. Brown offered a second amendment to allow individuals, without an economic interest in a pesticide, who are adversely affected by a decision of the Administrator following an interim administrative review proceeding to request a hearing. Mr. Brown explained that the amendment would require the individual that requests a hearing to have the burden of going forward to present an affirmative case and the burden of proof on the issue that gave rise to the request for a hearing. The Subcommittee agreed, by voice vote, to the Brown amendment.

Mr. Brown requested that three amendments be considered that relate to the compensation that must be paid by follow-on registrants for the use of health and safety data previously submitted to the agency by another registrant. Mr. Brown explained that the first amendment was identical to a bill, H.R. 4440, that he introduced earlier in this session of Congress. Mr. Brown said that the bill and the amendment reflect language that the Committee on Agriculture, and the House of Representatives, agreed to in 1982. Mr. Brown said tht H.R. 4440 was introduced with the desire that the interested parties work to reach an amicable solution to the data compensation issue.

Mr. Brown explained that the second amendment would resolve the data compensation question by providing that compensation would be paid based on the cost of developing the data rather than paying for the value of the data relative to the market developed for the product. Mr. Brown said that the amendment would resolve the data compensation question to the advantage of the follow-on registrants because the basis for arbitration would be the cost of the data to the original developer of the data.

Mr. brown explained that the third amendment would require the Administrator to pay a data submitter a sum certain for data when submitted, and thereafter the data would be in the public domain and available for disclosure on request. Mr. Brown stated that there is a certain reasonableness to the proposal because the health and safety data are generated to benefit the public and therefore should not be available for commercial exploitation. Mr. Brown said he could envision that a majority of the Members of

the House might be willing to accept this argument and vote for the amendment.

Mr. Brown summarized his comments by saying that the three amendments are worthy of discussion because they set the parameters of the debate on the issue of data compensation. Mr. Brown said that he wanted all the Members to be familiar with each alternative because it could be offered if no compromise is forthcoming. Mr. Roberts expressed his concern that the data compensation issue could threaten the entire progress of the bill. Mr. Roberts commented further that he agreed with Mr. Brown that follow-on registrants need to know what the data will cost before agreeing to pay. Mr. Roberts said he might offer an amendment to provide for non-binding arbitration prior to the time a person submits an application for registration. Mr. Roberts said this approach would avoid a rigid formula but would also provide the formulator some certainty about the cost of the data. Mr. Brown and Mr. Roberts agreed not to move the adoption of their amendments during Subcommittee consideration but to hold them for the Full Committee markup with the hope that further negotiated progress would be made on the issue. Mr. Gunderson said he was considering offering an amendment to require the Administrator to appoint a five-member panel to study the entire data compensation issue. Mr. Bedell expressed his concern that the study approach would provide a victory for those parties that do not wish to see any changes in the data compensation mechanism in the FIFRA. Mr. Bedell said that he would continue to work to resolve the problem.

Mr. Morrison offered an amendment to the provision in the Committee Print that would require the Administrator to issue regulations to protect employees that mix, load, and apply pesticides and employees that work in, pesticide-treated areas. Mr. Morrison explained that the amendment would allow the Administrator to issue the regulations if appropriate and necessary. After a discussion, the Subcommittee agreed to the Morrison amendment by voice vote.

Mr Morrison offered a second amendment to strike provisions in the Committee Print providing that the violation of certain regulations issued by the Administrator under the FIFRA would be considered a violation of the FIFRA and therefore subject to civil and criminal penalties. Mr. Morrison explained that the provisions of the Committee Print seem to require pesticide users not only to apply pesticides in accordance with their labeling, but also to comply with rules only published in the Federal Register. Mr. Morrison asked Dr. Moore if he had any comments on the subject. Dr. moore said that the agency supports the language in the Committee Print because, without penalties for noncompliance, adherence to the rule would be unlikely. Dr. Moore said that the agency would like to be able to issue regulations that are enforceable with some penalty. After further discussion, Mr. Morrison was allowed to withdraw the amendment to allow for further study.

Mr. Panetta offered an amendment to specifically authorize a currently funded program within the Department of Agriculture, known as the Interregional Project #4 (IR-4), which generates health and safety data for minor use pesticides that are used for agricultural purposes. Mr. Panetta said that the special authoriza-

tion is needed because, in the past, the Administration has not wanted to fund the program, but appropriation Acts have kept the program going. Mr. Panetta said that the IR-4 program is needed because it is beneficial to smaller growers in developing information needed for minor use pesticides. Mr. Morrison expressed his support for the IR-4 program and the amendment. Mr. Brown expressed his support for the amendment and offered to join Mr. Panetta in persuading the Appropriations Committee to continue funding the program. After further discussion, the Subcommittee agreed, by voice vote, to the Panetta amendment.

Mr. Evans of Iowa offered an amendment to direct the Administrator to contract with the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricultural commodities. Mr. Evans of Iowa explained that this type of information might allow a grower to evaluate the relative environmental risk of a variety of chemicals that would be effective in treating the same problem. After a discussion about the cost of the study, the Subcommittee agreed, without objection, to amend the proposal to allow the Administrator and the Academy to agree on the amount to be spent for the study. After further discussion, the Subcommittee agreed to the amendment, as amended, by voice vote.

Mr. Volkmer offered an amendment to modify the provisions in the Committee Print related to the certification and training of pesticide applicators to provide that only applicators of restricted use pesticides must be certified. Mr. Volkmer explained that this change was needed because the provisions in the Committee Print would seem to require anyone who uses a pesticide to be a certified applicator. After discussion of the amendment, the Subcommittee agreed, by voice vote, to the Volkmer amendment.

Mr. Bedell asked for further amendments. There was no response to the request for additional amendments. The Subcommittee then agreed, by voice vote, to substitute the text of the Committee Print for the text of H.R. 2482. Mr. Roberts moved that H.R. 2482, as amended, be reported to the Full Committee with a recommendation that the bill do pass.

By recorded vote of 13 yeas and no nays, the Roberts motion was agreed to by the Subcommittee in the presence of a quorum. The staff was authorized by unanimous consent to make any necessary clerical and technical changes.

Committee Markup

I

The Committee met on Thursday, June 5, 1986 in an open business meeting called to consider H.R. 2482, as reported by the Subcommittee on Department Operations, Research, and Foreign Agriculture. The Committee had before it a Committee Print containing the provision of the Subcommittee substitute for H.R. 2482.

After opening remarks by Chairman de la Garza, Mr. Bedell, and Mr. Roberts, the staff was asked to summarize the bill. After the staff presented a description of the major provisions of the bill, Dr.

John A. Moore, Assistant Administrator for Toxic Chemicals and Pesticides, Environmental Protection Agency (EPA), was asked by the Chairman to offer his comments on the pending bill. After Dr. Moore's comments, Mr. Bedell was recognized.

Mr. Bedell offered a package of technical amendments. Mr. Bedell explained that the amendments would simply clarify various provisions in the bill by incorporating corrections and further agreements. Mr. Bedell said that he was not aware of any controversy about any of the technical amendments. Mr. Roberts said the amendments are technical and would provide a clean bill for further markup. Mr. Combest, Mr. Roberts, and Mr. Morrison discussed with Dr. Moore provisions in the bill that would authorize the Administrator to issue regulations to protect workers from potentially harmful exposure to pesticides. The Committee agreed, by voice vote, to the technical amendments offered en bloc by Mr. Bedell. Chairman de la Garza requested that the staff promptly incorporate the amendments into a Committee Print to be available for the next meeting of the Committee.

II

The Committee met on Wednesday, June 11, 1986 for further consideration of H.R. 2482. Chairman de la Garza called up the bill and said that it would be open for amendment by title.

Mr. Hatcher offered an amendment that he described as an amendment to authorize the Administrator, in the Administrator's sole discretion, to waive reregistration fees for certain small businesses. Mr. Hatcher said that the amendment would define a small business as an unincorporated business, partnership, or corporation that has 125 or fewer employees and for the last 3 years had an average annual gross revenue that did not exceed $20,000,000. Mr. Bedell recommended that the Committee approve the amendment. Mr. Roberts said that he had no objection to the amendment. The Committee agreed to the Hatcher amendment by voice vote.

Mr. Stenholm offered an amendment to delete provisions in the bill that would allow individuals without an economic interest in a pesticide to request a hearing following a decision of the Administrator after a public interim administrative review. Mr. Stenholm said that eliminating the provision would keep individuals from asking for hearings based on frivolous grounds. Mr. Bedell offered a substitute for the Stenholm amendment. Mr. Bedell explained that the substitute would allow individuals without an economic interest to ask for a hearing, and the Administrator could grant the request for the hearing if it appears that the request presents a genuine and substantial issue of fact whether the pesticide poses an unreasonable risk to man or the environment.

After a discussion of the substitute the Committee agreed to suspend consideration of the amendment to allow Mr. Bedell and Mr. Stenholm time to discuss the issue.

Mr. Stenholm offered a second amendment to restrict authority to be granted the EPA in the bill to require label changes by rulemaking. Mr. Stenholm explained that under the amendment the Administrator could require changes to the labeling of a pesticide unless those changes are equivalent to a cancellation or they

render the product unmarketable or otherwise have a major adverse effect on adversely affected persons. Mr. Bedell said that he had no problem with the major thrust of the amendment, but that provisions for an automatic stay pending review of the regulation are objectionable. Mr. Glickman said that any label change requirement could have a major effect on some adversely affected person, so the amendment would severely restrict the Administrator's ability to make label changes by rulemaking. Mr. Stenholm said that hearing and cancellation procedures should be used, not rulemaking, when the Administrator proposes to restrict the use of a pesticide that is causing unreasonable harm to the environment. Mr. Stangeland spoke in support of the Stenholm amendment. When asked to comment by Members of the Committee, Dr. Moore said the Agency would like additional authority to make label changes by rulemaking. Dr. Moore said the Agency would prefer the language in the bill over that proposed by Mr. Stenholm.

Mr. Bedell offered an amendment to the Stenholm amendment to specify that a stay of the regulation requiring a label change would only be available if requested. Mr. Brown spoke in opposition to the Stenholm amendment.

Mr. Madigan pointed out that the language in the bill and the Stenholm amendment would provide new authority and not weaken any authority available to the Administrator under current law. Mr. Madigan asked Dr. Moore to confirm that the Stenholm amendment would grant the Administrator new authority. Dr. Moore agreed that the amendment would seem to grant new authority. Mr. Marlenee spoke in support of the Stenholm amendment.

Mr. Stenholm said he would accept the amendment to his amendment, as suggested by Mr. Bedell, to make the stay provision available only if requested by the petitioner. After further discussion the Committee agreed, by voice vote, to the Bedell amendment. The Committee then agreed, by a show of hands vote, 16 yeas and 5 nays, to the Stenholm amendment, as amended.

Mr. Morrison offered an amendment to amend section 24(c) of the Act to deny States the authority to use lack of essentiality as the sole criterion in determining whether or not to issue a registration for additional uses of a federally registered pesticide, formulated for distribution and use within that State, to meet special local needs. Mr. Morrison explained that a State will often deny a registration to meet special local needs because use of one particular pesticide is not essential, that is, some alternative registered pesticide is available. Mr. Morrison said that use of this rule, without exceptions, causes several problems. First, it encourages monopolies to exist because only one pesticide can be approved for a particular purpose. Second, it does not allow for the use of alternative pesticides to avoid or overcome the development of pesticide resistance. Third, it does not encourage the development of alternative pesticides. Fourth, it does not allow for the use of alternative pesticides that remain safe when foods are processed. Mr. Brown said that it was a good idea to call the attention of the States to the need to use sound judgment in their decisions on special local needs registrations, but that further study of the proposal might be desirable. Mr. Morrison agreed that eliminating the ability to use

the essentiality criterion in all cases might not be desirable. Mr. Morrison asked permission to withdraw the amendment and that, in lieu of the amendment, the Committee express its views on encouraging States to make limited use of the essentiality criterion. Without objection, Mr. Morrison was allowed to withdraw the amendment and the Committee so agreed.

Mr. Stenholm asked that the Committee resume consideration of his first amendment, to strike provisions in the bill allowing individuals without an economic interest in a pesticide to ask for a hearing following a public interim administrative review. Mr. Bedell offered a substitute to allow individuals without an economic interest to ask for a hearing, but the hearing would be held only if the request presented a genuine and substantial issue of fact whether the pesticide poses an unreasonable risk to the environment. Mr. Madigan asked for unanimous consent to amend the substitute to clarify that the Administrator would determine whether a substantial issue of fact had been presented. The Madigan amendment was agreed to without objection. The Committee agreed to the Bedell substitute, as amended, by voice vote.

Mr. Stenholm offered a third amendment to delete provisions in the bill providing that violation of a regulation issued under certain subsections of the Act would be considered a violation of the Act, and therefore subject to penalty. Mr. Stenholm said that the provisions in the bill would create a problem for pesticide users because they would be forced to follow both label directions and regulations issued by the EPA. Mr. Stenholm said that he did not believe that providing the EPA with the additional authority was necessary. Mr. Bedell wanted to know the EPA's view of the amendment. Dr. Moore responded that the agency would especially like the enhanced enforcement authority, as provided in the bill, for sections 3(a), 19(a), and 25(c)(3) of FIFRA. Mr. Roberts commented that he and other Members had worked with Dr. Moore to narrow the original EPA proposal on enforcement of regulations to the specific sections outlined by Dr. Moore. Mr. Panetta expressed his desire that EPA be given as much authority as possible to enable it to take the lead in the regulation of biotechnology. Mr. Madigan said he absolutely concurred with the remarks of Mr. Panetta. After further discussion of the amendment, the Committee agreed, without objection, to modify the amendment so that references only to sections 3(a), 19(a), and 25(c)(3) of FIFRA would be retained in the bill. Without objection, the Committee agreed to the Stenholm amendment, as amended.

Mr. Morrison offered an amendment to substitute for provisions in the bill authorizing the Administrator to issue regulations to protect workers from exposure to pesticides. Mr. Morrison also asked that the Committee adopt an expression of its intent regarding the amendment. Mr. Morrison said that the amendment was the result of a compromise between a number of competing interests. Mr. Morrison explained that the compromise would not require the EPA to establish a special office on worker health and safety, as required in the bill, but protective regulations would be mandated. Mr. Morrison said the amendment would exempt employees exposed to pesticides as a result of pesticide use on livestock or other animals. Mr. Bedell and Mr. Roberts complimented

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Mr. Morrison for his work on the amendment, and urged the Committee to adopt the proposal. Mr. Huckaby asked whether the requirements in the amendment would mean changing standard agricultural practices anywhere in the United States. Dr. Moore said that he did not believe the requirements would generally result in change of standard practices. Mr. Roberts said that he and other Members of the Committee would be taking a long and close look at any proposed regulations, especially in regard to the possible concerns of Mr. Huckaby.

The Committee agreed, by voice vote, to the Morrison amendment. The Committee agreed, without objection, to the Committee intent proposal, which apears in the Section by Section Analysis section of this report.

Mr. Bedell offered a technical amendment to redraft the provisions in the bill requiring the cancellation or revocation of tolerances or exemptions from tolerances when the registration of a pesticide is cancelled or suspended. Mr. Bedell explained that the amendment was offered at the request of Members of the Committee on Energy and Commerce. Mr. Bedell said that the amendment would make the provision an amendment to the Federal Food, Drug, and Cosmetic Act. The Committee agreed, by voice vote, to the Bedell amendment.

Mr. Stenholm offered a fourth amendment to delete provisions in the bill that would preclude judicial review of EPA regulations once an enforcement action had begun if the regulations could have been challenged previously. Mr. Stenholm said that the bill language would not provide adequate protection for parties adversely affected by EPA regulations. Mr. Bedell asked that the EPA be allowed to state its views on the amendment. Dr. Moore said the agency supported the language in the bill without the amendment. Dr. Moore explained that after the promulgation and review of a regulation it should not be subject to limitless challenges in actions brought to enforce the regulation. Mr. Bedell suggested that the answer to Mr. Stenholm's concern would be to lengthen the amount of time available for an initial challenge of the regulation. Mr. Huckaby spoke in support of the Stenholm amendment. Mr. Volkmer commented that under the bill anyone, at any time, could file a petition to modify or repeal the regulation, and if the EPA refused the petition, that refusal could be reviewed by a court. Mr. Bedell suggested that the period for challenging the regulation be expanded from the 60 days provided in the bill to 120 days. Mr. Stenholm said that even if the period for challenges was expanded, it would not address the concern that a party should be able to challenge the regulation in the enforcement proceeding. Mr. Madigan said that because of the constantly evolving nature of science, there should not be a limit on the time to challenge a regulation. Mr. Volkmer said that under the terms of the bill, the regulation could always be reviewed through a petition to modify, in which case a party might have simultaneous actions. After further discussion, the Committee adjourned.

III

The Committee reconvened on Thursday, June 12, 1986, and agreed to temporarily defer consideration of the Stenholm amendment.

Mr. Bedell offered an amendment to terminate the primary enforcement responsibility of a State under the FIFRA on January 1, 1989, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided under FIFRA. Mr. Bedell explained that the amendment would help to standardize penalties for violations of the Act. The Committee agreed to the Bedell amendment by voice vote.

Mr. Stenholm was recognized for further consideration of the review of regulations amendment. Mr. Stenholm said that he believed the language in the bill should be struck and urged the Members to support the amendment. Mr. Bedell asked for unanimous consent to modify the bill to provide that the period for review of regulations in the bill be extended from 60 days to 120 days. Without objection the Committee agreed to the Bedell amendment.

Mr. Bedell then offered a substitute for the Stenholm amendment. Mr. Bedell explained that the substitute would address one of the concerns articulated by Members of the Committee by allowing farmers to challenge a regulation in the enforcement proceeding. Mr. Madigan said that the effect of the substitute would be to duplicate provisions of law used in other environmental statutes, except that an exemption would be provided for agricultural producers. After further discussion, the Committee agreed to the Bedell substitute, by recorded vote, 16 yeas and 12 nays.

Mr. Stenholm was granted unanimous consent to offer an amendment to the Bedell substitute to provide that when an adversely affected person petitions to modify or rescind a regulation, the application of the regulation to the person would be stayed until the Administrator issues a final decision on the petition. Mr. Bedell said he could agree to the amendment. Without objection, the Committee agreed to the Stenholm amendment. The Committee agreed to the Stenholm amendment, as amended by the Bedell substitute.

Mr. Bedell offered an amendment to substitute for the provision in the bill requiring the Administrator to regulate the contamination of groundwater by pesticides. Mr. Bedell said the amendment would provide that the Administrator must, as appropriate and necessary, use the authorities under the Act to provide for the protection of groundwater against contamination by pesticides. Mr. Bedell further explained that the amendment would require the Administrator to consult with the States regarding the appropriate means for monitoring and controlling pesticide contamination in groundwater.

Mr. Evans of Iowa said he has grave concerns about the regulation of pesticides as it relates to the contamination of groundwater. Mr. Evans of Iowa said that he has seen an EPA proposal that provided, if a pesticide was detected in well water, the use of the pesticide would be arbitrarily banned within the radius of two miles of the well. Mr. Evans of Iowa said that such a proposal would be dis-

asterous for farmers in the United States. Mr. Evans of Iowa explained that such a simple device must have been suggested by someone without any knowledge of how groundwater contamination occurs. Mr. Evans of Iowa said that pesticide contamination in wells does not originate anywhere near the site of the well. Mr. Evans of Iowa further explained that in his area of Iowa the soils are underladen with thick layers of impervious clay, and contaminants get into groundwater many miles away where soil is thin, for example, underlain by fractured limestone.

Mr. Madigan commented that the purpose of the Bedell amendment was to simply have some language in the bill regarding the protection of groundwater. Mr. Madigan said he was concerned that even though the intention of the Members is to develop a more complete groundwater provision, the amendment may survive consideration by the House without change. Mr. Madigan said that he did not want to empower the Administrator to ban a pesticide product to prevent contamination of groundwater, without regard to the seriousness of the contamination. Mr. Penny expressed his desire that EPA develop a policy, in cooperation with the States, that will be reasonable and take into consideration the type of agriculture, soil types, and other differences in various parts of the country. Mr. Roberts explained that the language in the bill was agreed to by a number of industry, environmental, and farm groups but has been opposed by the EPA and other environmental groups. Mr. Roberts further explained that staff had been instructed to draft a provision with the understanding that an amendment would be offered on the floor representing a final resolution of the issue. Mr. Evans of Iowa offered a substitute for the Bedell amendment. Mr. Evans of Iowa explained that the substitute would require consultation with the Secretary of Agriculture, as well as consultation with the States. Mr. Evans of Iowa further explained that the substitute would require the use of maximum contaminant levels established under the Safe Drinking Water Act as a guide. Mr. Smith asked Dr. Moore if the substitute would provide additional or new authority to the Administrator. Dr. Moore responded that the Agency feels that it has authority under current law, and is acting to control the potential for pesticides under certain conditions of use to make their way into groundwater at a level that may cause unreasonable environmental concerns. Dr. Moore said the substitute only makes explicit the authority to regulate pesticidal contamination of groundwater. After a discussion of the amendment, the Committee agreed, by voice vote, to the Evans of Iowa substitute for the Bedell amendment.

Mr. Volkmer offered an amendment to substitute for provisions in the bill related to the certification, training, and recordkeeping of pesticide applicators and dealers. Mr. Volkmer said the amendment represents a compromise reached by a number of interested parties. Mr. Volkmer then offered a technical amendment to his amendment. Without objection, the Committee agreed to the Volkmer technical amendment.

Mr. Emerson offered an amendment and a proposed Committee position statement. Mr. Emerson explained that the position statement was designed to clarify that certification and training should be required for persons that use pesticides on more than just an

occasional basis, but that training should not be required for the neighborhood youth who mows lawns in the summer. Mr. Volkmer commended Mr. Emerson for the proposal.

Mr. Emerson and Mr. Volkmer discussed the problem of reciprocity in training requirements between States. Mr. Emerson said that his congressional district borders on four different States, and unless the States have reciprocity, it might be necessary for an applicator to go through separate training in each of the four States. Mr. Emerson expressed his desire that the EPA act as a coordinating agency to facilitate and expedite the establishment of reciprocity. Mr. Volkmer said he agreed that the reciprocity problem needs to be addressed and expressed his willingness to work to find a satisfactory solution. Dr. Moore expressed his willingness on behalf of the EPA to work with Mr. Volkmer and Mr. Emerson, along with the appropriate State officials, to resolve the reciprocity problem. Dr. Moore said he had no objection to the proposed position statement. Without objection, the Committee agreed to it, and it appears in the Section-by-Section Analysis section of this report.

Mr. Emerson explained that the pending amendment, regarding enforcement officer training, would require field personnel who are responsible for on-site observations and inspections to have had the same training as those applicators who actually use the pesticide. Mr. Emerson said that enforcement officer training is not what it should be in some States and the amendment would help correct problems that may exist. Mr. Huckaby expressed his support for the amendment. The Committee agreed, by voice vote, to the Emerson amendment to the Volkmer amendment.

Mr. Stangeland offered an amendment to the Volkmer amendment regarding records of pesticide dealers and applicators. Mr. Stangeland explained that his amendment would minimize the amount of these records that State agencies would be required to keep in order to provide access to a complainant. Mr. Stangeland said that many State departments of agriculture strongly support the amendment. Mr. Volkmer said he could agree to the amendment. Without objection the Committee agreed to the Stangeland amendment to the Volkmer amendment. The Committee then agreed to the Volkmer amendment, as amended, by voice vote.

Mr. Marlenee offered an amendment to provide that, notwithstanding any other provision of law, no attorneys' fees or expenses could be awarded for any civil action brought under the reregistration provisions in the bill. Mr. Marlenee said that the amendment was needed in order to keep agency resources, provided in part by user fees, that will be passed on to agricultural producers, from being depleted through awards of attorneys' fees in suits brought for the failure to meet one of the many deadlines in the reregistration provisions. Other Members of the Committee argued against the Marlenee amendment, reasoning that the recovery of attorneys' fees under the Equal Access to Justice Act requires the prevailing party to prove that the agency action was substantially unjustified, and it is fair under those limited conditions to grant an award of attorneys' fees. Mr. Stenholm offered a substitute to not allow judicial review of any final decisions made by the Administrator under the reregistration provisions of the bill. After a discus-

sion, the Committee, by voice vote, did not agree to the Stenholm substitute for the Marlenee amendment.

Mr. Roberts offered an amendment to the Marlenee amendment to clarify that the ban on awards of attorneys' fees would only apply in suits brought for failure to meet deadlines. The Committee, by voice vote, agreed to the Roberts amendment. By recorded vote, 19 yeas and 22 nays, the Committee did not agree to the Marlenee amendment, as amended.

Mr. Weaver offered an amendment to require the EPA to collect and analyze samples of human breast milk for residues of chlorinated dioxins and report to Congress, not later than two years after the bill's enactment, on the results of the analysis. Mr. Weaver said that the study is needed becaue previous studies have not been directed specifically at the question of dioxins in mothers' milk. The Committee agreed, by voice vote, to the Weaver amendment.

Mr. Glickman offered an amendment to require the Administrator to promulgate regulations, after consultation with appropriate Federal agencies, to establish appropriate application techniques and restrictions to control pesticide drift, such as appropriate site restrictions that take into account the areas that may be affected by the pesticide. After a discussion of the amendment, the Committee allowed Mr. Glickman to withdraw the amendment, to provide Members an opportunity for further study of the pesticide drift question. Without taking further action, the Committee adjourned.

IV

The Committee reconvened on Tuesday, June 17, 1986, for further consideration of H.R. 2482. Mr. Morrison was recognized to offer a proposed statement of Committee position regarding the use of lack of essentiality as the sole criterion by States in reviewing applications for registrations to meet special local needs, under section 24(c) of the FIFRA. Mr. Brown said he had no objection to the proposal. Without objection, the Committee agreed to the Morrison proposal, which follows:

LACK OF ESSENTIALITY

Lack of essentiality is a term applied to a regulatory criterion for denying approval for a pesticide merely because an alternative is available. Congress barred EPA from using "lack of essentiality" as a criterion in denying the registration of a pesticide when FIFRA was amended in 1972 (cf. Section 3(c)(5)). Prohibiting use of "lack of essentiality" as the sole criterion is justified for several compelling reasons:

(1) It precludes government-sanctioned monopolies that would exist if only one pesticide can be approved for a particular purpose.

(2) It allows use of alternative pesticides to avoid or overcome the development of resistance by pests.

(3) It encourages development of new alternative pesticides.

(4) It allows use of alternative pesticides which remain safe when foods are processed.

Some States apply or are threatening to apply a criterion of lack of essentiality in regulating pesticides. For example, in Texas in the late 1970's, food processors ran into a problem when the state refused registration based on lack of essentiality for a pesticide that was safe for use on spinach to be processed. The Food and Drug Administration discovered that the pesticide approved for use by the State was unsafe for processing operations since it broke down during heating into possible carcinogens. The problem was eventually resolved but not during that particular growing season.

It is the sense of the Committee that the reasons for denying lack of essentiality at the Federal level are equally valid at the State level, and the Committee urges the states to take these reasons into consideration.

Mr. Glickman offered an amendment to require the Administrator, within two years after the bill's enactment, to report to the House and Senate Agriculture Committees on the incidence and potential adverse effects on human health and the environment that may result from the drift of pesticides from the site of application. Mr. Glickman said that he was proposing a study in lieu of his earlier proposal to require the Administrator to promulgate regulations regarding pesticide drift. Mr. Morrison expressed his desire that the study include an evaluation of the training of applicators in the control of pesticide drift. Mr. Morrison explained that an emphasis on training of applicators might help to control drift and any potential adverse effects, thus solving a major part of the problem. Mr. Glickman said that Mr. Morrison's suggestion should be at the heart of the study. Mr. Thomas said pesticide drift is mostly dependent on weather conditions, and this aspect of the problem should be closely studied. After further discussion, the Committee, by voice vote, agreed to the Glickman amendment.

Mr. Bedell offered an amendment to provide a four-year authorization for appropriations under FIFRA. Mr. Roberts offered an amendment to the Bedell amendment to provide a five-year authorization. Mr. Roberts said that a four-year authorization would mean that FIFRA would expire the same year as the 1985 farm bill. Mr. Roberts said that it would be unfortunate if the next review of FIFRA was not given the full attention of the Committee due to the need to reauthorize the farm programs. Mr. Bedell expressed his support for the Roberts amendment. Mr. Madigan asked how the proposed authorization levels in the amendments compare with the current authorization for the present fiscal year. Mr. Bedell said that the authorization for the current fiscal year is $68 million, and his amendment would provide an authorization of $72 million for the next fiscal year. Mr. Madigan expressed concern that because the authorization in the Bedell amendment increased from the current level of $68 million to a level of $106 million in fiscal year 1991, the Administration may oppose the bill. Mr. Madigan noted that amendments to freeze authorizations have been successful on the floor of the House in the past. Mr. Madigan asked the EPA representative if the proposed authorization levels would be supported by the Administration. Ms. Susan Sherman, Deputy Director, Office of Pesticide Programs, EPA, responded that Dr. Moore would do everything possible to ensure that the Administra-

tion will support the authorization levels in the Bedell amendment. Mr. Roberts said that the reregistration fees required in the bill would raise $42 million, and because the new reregistration program has been estimated to cost an additional $96 million, additional fees would be required or additional sums over the current baseline would need to be authorized by the Committee. Mr. Gunderson said that his private conversations with Dr. Moore lead him to believe that unless additional fees are included in the bill, the Office of Management and Budget will oppose the bill. After a discussion, the Committee agreed to the Roberts amendment, as amended, by voice vote.

Mr. Glickman offered an amendment to substitute for provisions in the bill regarding requirements for the Administrator to regulate inert ingredients in pesticides. Mr. Glickman said the amendment reflected an agreement that had been reached between many of the parties interested in the FIFRA reform effort. Mr. Glickman said that the amendment will ensure that EPA stays on its current plan to evaluate and test inert ingredients. Mr. Roberts said that he had no objection to the amendment. Mr. Roberts asked that the Committee adopt a statement of position regarding the construction of provisions in the inerts section. Without objection, the Committee agreed to the proposal, which appears in the Section-by-Section analysis of this report. The Committee then agreed, by voice vote, to the Glickman amendment.

Mr. Madigan offered an amendment to require the Comptroller General to conduct an evaluation of the programs and activities authorized under the bill, and to make a report to Congress no later than December 31, 1988, regarding the effect that the FIFRA, as amended by the bill, is having on the cost and availability of pesticides to producers of food and fiber. Mr. Madigan explained that the evaluation would include an analysis of the reregistration and any groundwater programs conducted by the EPA. The Committee agreed to the Madigan amendment by voice vote.

Mr. Stenholm offered an amendment to substitute for provisions in the bill authorizing the Administrator to make label changes by rulemaking. Mr. Stenholm said the amendment would correct problems with the amendment previously adopted by the Committee regarding this provision, and had been agreed to by all the interested parties. Mr. Brown said he supported the amendment. Without objection, the Committee agreed to the Stenholm amendment.

Mr. Bedell offered an amendment to provide for the apportionment of reregistration fees among registrants of pesticides containing the same active ingredient. Mr. Bedell explained that the amendment would authorize the Administrator to apportion reregistration fees for reregistration among the registrants of pesticides containing the same active ingredient, and if one registrant does not pay the apportioned fee, then that registration would be cancelled, and the fee would be reapportioned among the remaining registrants. Mr. Bedell said that the amendment had been agreed to by the interested parties, including the EPA. After a discussion of the amendment, and the possible shortfall that may be created because the total amount of reregistration fees may not cover the entire costs of the reregistration program required in the bill, the

Committee agreed, by voice vote, to the Bedell amendment, and adjourned for the day.

V

The Committee reconvened on Wednesday, June 18, 1986, for further consideration of H.R. 2482. Mr. Jeffords offered an amendment to rewrite provisions in the bill related to the Occupational Safety and Health Act (OSHA) as it affects the ability of the Secretary of Labor to take regulatory action on a subject regulated by the Administrator. Mr. Jeffords explained that under OSHA, actions by the Administrator can possibly preempt the Secretary of Labor from taking regulatory action, and uncertainty over which agency has authority to regulate can leave some individuals caught in the middle without protection. Mr. Jeffords said that the amendment would help solve this problem by requiring the Administrator and the Secretary of Labor to reach agreements and coordinate the exercise of their statutory authority. Mr. Bedell expressed his support for the amendment. The Committee agreed, by voice vote, to the Jeffords amendment.

Mr. Jeffords then offered a proposed statement of Committee position regarding the preemption question under the OSHA, and requirements in the bill concerning Material Safety Data Sheets. The Committee agreed, without objection, to the Jeffords proposal, which appears in the Section-by-Section Analysis section of this report.

Mr. Stangeland offered an amendment to specify that registrants of pesticides that contain an active ingredient for which the EPA has issued a registration standard must pay a reregistration fee of $150,000, rather than the $100,000 fee provided in the bill. Mr. Stangeland said that the amendment would raise an additional $6.35 million to help offset the costs of the reregistration program. Mr. Bedell said that he could not support the amendment because it might upset the compromise in the bill. Mr. Gunderson expressed concern that the possible shortfall in revenue be addressed before sending the bill to the floor. Mr. Bedell said that he did not disagree that additional revenue might be needed, but the Stangeland amendment would not offer enough revenue. After further discussion, the Committee, by recorded vote, 20 yeas and 21 nays, did not agree to the Stangeland amendment.

Mr. Stangeland offered a second amendment to require that a reduced fee be paid by registrants of pesticides registered for uses other than on food or feed. Mr. Stangeland said that the reduced fee, for pesticides not used on food or feed, is equitable because the reregistration of these pesticides requires less agency time and effort. Mr. Bedell argued in opposition to the amendment, saying that the bill currently provides authority for the Administrator to waive the fees for pesticides registered for uses other than on food or feed. The Committee, by show of hands, 9 yeas and 10 nays, did not agree to the Stangeland amendment.

Mr. Evans of Iowa offered an amendment to require the Administrator to conduct a survey to determine what research has been, or is being, conducted to establish the extent to which agents that act as pesticides are manufactured by plants and thereby exist nat-

urally in the fruits, vegetables, grains, legumes, and oilseeds commonly consumed by persons in the United States. Mr. Evans of Iowa said that the EPA had no objections to conducting the survey. Mr. Brown said the survey would provide very important and useful information. Mr. Bedell expressed concern that the results of the survey could be used to discourage people from consuming a variety of agricultural crops. The Committee agreed to the Evans of Iowa amendment by voice vote.

Mr. Brown offered an amendment related to the allocation of the costs of generating health and safety data to maintain an existing registration of a pesticide. Mr. Brown said that the cost-sharing mechanism contained in the amendment had been agreed to by the interested parties. Mr. Bedell urged the Committee to adopt the amendment. The Committee agreed to the Brown amendment by voice vote.

Mr. Brown offered a second amendment to provide that the cost of health and safety data to a follow-on registrant will be decided in an arbitration proceeding, and the award would be based on a fair apportionment of the cost of developing the data by the original data submitter. Mr. Brown said the amendment provides a simple and reasonable approach to solving the data compensation issue. Mr. Rose argued against the amendment, saying that data developers spend a great deal of money, up to 10 percent of their budgets, on research and development, and they deserve more than a cost-based data compensation rule. Mr. Brown asked if any of the agency's representatives knew how the data compensation procedure worked prior to the 1978 FIFRA amendments. Mr. Edward Gray, from the Office of the General Counsel, EPA, responded that prior to 1978, an administrative law judge would make the compensation decision, based on the cost of developing the data.

Mr. Rose offered a substitute for the Brown amendment. Mr. Rose explained that the amendment would require the use of cost-based compensation formula, as determined in arbitration, equal to the cost of developing the data plus an additional sum not to exceed the cost of the data. Mr. Rose said this formula would come into being if the term of the patent for the pesticide is extended by the operation of an Act of Congress passed after the FIFRA amendments, that includes a provision to authorize the extension of unexpired pesticide patents regardless of when the regulatory review process began for that pesticide. Mr. Rose said the amendment would also provide that for pesticides with expired patents, a special non-binding arbitration proceeding could be requested by a person before submission of the application for a follow-on registration. The arbitration would be binding on the original data submitter and non-binding on the data seeker until the application for registration is submitted, Mr. Rose said. Also under the amendment, Mr. Rose told the Committee, in any subsequent non-binding arbitration proceeding, a data seeker would have to pay all costs for the arbitration, including attorneys' fees for both parties.

Mr. Huckaby offered an amendment to the Rose substitute. Mr. Huckaby explained the amendment would provide that any time three years after the patent for a pesticide expires, the amount of compensation will be determined in arbitration, and the maximum amount of compensation will be twice the cost of developing the

data. Mr. Huckaby said that his each follow-on registrant of the pesticide would be liable for twice the cost of the data. Mr. Huckaby said that amendment would help get less expensive generic chemicals to the Nation's farmers. Mr. Hatcher spoke in favor of the Huckaby amendment. Mr. Hatcher said that he has seen the price of a particular pesticide used on peanuts fall from $21 to $5 per gallon because of the competition generated by the entry of a follow-on registrant into the market. Mr. Evans of Iowa commented that generic pesticides are available in other countries at much lower prices than in the United States.

Mr. Brown expressed concern that because the Huckaby amendment requires each follow-on registrant to pay up to twice the cost of the data, the data submitter might end up receiving 40 times the cost of the data. To reduce the amount of possible compensation, Mr. brown asked for unanimous consent to offer an amendment to the Huckaby amendment to provide that maximum liability of each follow-on registrant would be for the cost of developing the data. Without objection, Mr. Brown was allowed to offer the amendment. The Committee agreed, by voice vote, to the Brown amendment to the Huckaby amendment. By recorded vote of 19 yeas and 23 nays, the Committee did not agree to the Huckaby amendment, as amended. By show of hands vote, 18 yeas and 8 nays, the Committee agreed to the Rose substitute. By voice vote the Committee agreed to the Brown amendment as substituted by the Rose amendment.

Mr. Roberts offered an amendment to provide for national uniformity in the regulation of the levels of pesticide residues in or on food. Mr. Roberts explained the amendment would provide for Federal tolerances to prevail over a State-established tolerance if a pesticide has completed registration, or if it is registered after April 25, 1986. Mr. Roberts said that rather than preempting State law, the amendment would provide for a Federal-State cooperative approach. States would also be allowed to petition the EPA to establish a lower tolerance, Mr. Roberts said. Mr. Roberts said that the amendment is needed to facilitate commerce among the States. Mr. Brown argued against the amendment, saying that a State should have the prerogative to have a higher standard. Several Members expressed reservations about the amendment due to potential jurisdictional overlap with another Committee of the House. After further discussion, the Committee agreed, by recorded vote, 31 yeas and 9 nays, to the Roberts amendment. Mr. Stenholm, having voted in the majority, moved to reconsider the vote taken on the Roberts amendment. By voice vote, the Committee agreed to reconsider the vote taken on the Roberts amendment. By voice vote, the Committee did not agree to the Roberts amendment.

Mr. Morrison offered a proposed statement of Committee position, that nothing in the provisions of the bill regarding the liability of agricultural producers may be construed to grant a cause of action under the FIFRA. The Committee agreed, without objection, to the Morrison position statement, which appears in the Section-by-Section Analysis section of this report.

Mr. Bedell moved that H.R. 2482, as amended, be reported to the House with a recommendation that the bill do pass. The Committee, in the presence of a quorum and by recorded vote, 42 ayes and

1 nay, agreed to the motion made by Mr. Bedell. Under unanimous consent, the staff was authorized to make any necessary clerical and technical changes to the bill or its report.

EXCHANGE OF LETTERS REGARDING PROVISIONS OF THE BILL

Hon. E DE LA GARZA,
Chairman, Committee on Agriculture,
Longworth House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: The Committee on Agriculture has ordered reported the bill H.R. 2482, the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986". As you know, there are two provisions in the bill of jurisdictional concern to the Energy and Commerce Committee. They are section 307 dealing with tolerances for pesticide residues on food, and section 716 dealing with groundwater contamination from pesticides.

Section 307 requires the Administrator of the Environmental Protection Agency to take certain actions regarding tolerances under section 408 of the Federal Food, Drug and Cosmetic Act. As you know, the provision was included in the bill as reported from the Subcommittee on Department Operations, Research and Foreign Agriculture as an amendment to FIFRA. Because this Committee's jurisdiction covers provisions affecting tolerances for pesticide residues in food, I appreciate that the provision was altered in your Committee's deliberations to amend section 408 of the FFDCA, since its sole effect was to require action under that section.

Section 716 requires the Administrator of EPA to take certain actions to protect the nation's groundwater and drinking water. It is my understanding that the Agriculture Committee intends to develop a more detailed provision which will be offered as a substitute for section 716 during floor consideration.

This section overlaps with, and the substitute provision which will be offered on the floor potentially overlaps with, our jurisdiction over the Safe Drinking Water Act and its requirements for EPA to guard the nation's groundwater and drinking water against contamination. To ensure that the proposal will be consistent with the groundwater program in the "Safe Drinking Water Act Amendments of 1986", which were enacted on June 19, 1986, I appreciate your assurances that the Committee on Agriculture will consult and cooperate with the Committee on Energy and Commerce in developing the groundwater proposal.

Our Committee recognizes the difficult task the Agriculture Committee faces in undertaking a substantial revision of FIFRA. We want to work with your Committee to facilitate the consideration of H.R. 2482 by the Congress, and to that end will not request sequential referral of the bill. Of course, in taking this action the Energy and Commerce Committee does not cede our jurisdiction over these or other related matters in conference.

Sincerely,

JOHN D. DINGELL, *Chairman.*

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, DC, July 18, 1986.

Hon. JOHN DINGELL,
Chairman, House Committee on Energy and Commerce,
Washington, DC.

DEAR MR. CHAIRMAN: Thank you for your letter noting the interest of the Committee on Energy and Commerce in certain provisions of H.R. 2482, the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

The Committee on Agriculture has devoted a great amount of time and effort, over the past several years, considering proposals to update and improve the operation of the pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act. H.R. 2482, as ordered reported by the Committee, is a sound package of amendments to the Act to strengthen the pesticide program, and we plan to make every effort to ensure that H.R. 2482 is enacted into law in the 99th Congress. In that regard, we are grateful for your indication of your willingness to work with the Agriculture Committee to facilitate the consideration by Congress of this important legislation.

H.R. 2482 was referred solely to the Committee on Agriculture under House Rule X(1)(a), which gives the Committee jurisdiction over agricultural and industrial chemistry and the marketing of agricultural products and commodities. However, with respect to the provisions of H.R. 2482 that you noted involve matters within the jurisdiction of the Committee on Energy and Commerce, we appreciate your cooperation in handling those provisions without the need for requesting a sequential referral of the bill. I understand that such action does not indicate an abdication of the jurisdictional interests of the Committee on Energy and Commerce. In addition, we intend to work with you to develop an amendment to protect groundwater from pesticide contamination that complements the Safe Drinking Water Act.

Sincerely,

E (KIKA) DE LA GARZA,
Chairman.

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON EDUCATION AND LABOR,
Washington, DC, June 19, 1986.

Hon. E DE LA GARZA,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: I am writing with regard to provisions in H.R. 2482, a bill to reauthorize the Federal Insecticide, Fungicide, and Rodenticide Act, which has been ordered reported by the Committee on Agriculture.

Section 815 of the bill provides for the establishment and maintenance of an occupational safety and health program for workers engaged in the mixing, loading, or application of pesticides, and workers exposed to pesticides.

Section 812 of the bill provides for a waiver of section 4(b)(1) of the Occupational Safety and Health Act (OSH Act), to allow the Occupational Safety and Health Administration (OSHA) to exercise regulatory authority in certain areas pursuant to a cooperative agreement between the Administrator of the EPA and the Secretary of Labor.

As you know, the Occupational Safety and Health Act, and matters relating to the safety and health or workers in general are within the jurisdiction of the Committee on Education and Labor. Though I have no objection to the inclusion of the above described provisions in H.R. 2482, I do want to make it clear that this acquiescence to the action of the Committee on Agriculture does not in any manner indicate an abdication of the jurisdiction of the Committee on Education and Labor over worker safety and health in general and the OSH Act in particular. I request that you include this letter in the report to accompany H.R. 2482.

I appreciate your cooperation in this matter.

Sincerely yours,

AUGUSTUS F. HAWKINS,
Chairman.

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, DC, July 11, 1986.

Hon. AUGUSTUS F. HAWKINS,
Chairman, House Committee on Education and Labor,
Washington, DC.

DEAR MR. CHAIRMAN: Thank you for your letter noting the interest of the Committee on Education and Labor in certain provisions of H.R. 2482, the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

The Committee on Agriculture has devoted a great amount of time and effort, over the past several years, considering proposals to update and improve the operation of the pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act. H.R. 2482, as ordered reported by the Committee, is a sound package of amendments to the Act that will strengthen the pesticide program, and we plan to make every effort to ensure that H.R. 2482 is enacted into law in the 99th Congress. In that regard, we appreciate your willingness to work with members of this Committee to construct the best possible legislative proposal.

H.R. 2482 was referred solely to the Committee on Agriculture under House Rule X(1)(a), which gives the Committee jurisdiction over legislation affecting agricultural and industrial chemistry. Nonetheless, I acknowledge your concern that provisions in the bill may affect the jurisdiction of the Committee on Education and Labor, and we are grateful for your cooperation in reviewing those provisions without requesting a sequential referral of the bill. I understand that such action does not indicate an abdication of any possible jurisdictional interest of the Committee on Education and

Labor. Your letter and this response will be included in the Committee's report on H.R. 2482.

Sincerely,

E (KIKA) DE LA GARZA,
Chairman.

ADMINISTRATION POSITION

At the time of the filing of this report, the Committee had not received a report from the Environmental Protection Agency or the U.S. Department of Agriculture concerning H.R. 2482, as amended. The views of the Administration are reflected in the Committee Consideration section of this report.

BUDGET ACT COMPLIANCE (SECTION 308 AND SECTION 403)

The provisions of clause 2(l)(3)(B) of Rule XI of the Rules of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 (relating to estimates of new budget authority or new or increased tax expenditures) are not considered applicable. The estimate and comparison required to be prepared by the Director of the Congressional Budget Office under clause 2(l)(3)(C) of Rule XI of the Rules of the House of Representatives and section 403 of the Congressional Budget Act of 1974 submitted to the Committee prior to the filing of this report are as follows:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 14, 1986.

Hon. E DE LA GARZA,
Chairman, Committee on Agriculture, House of Representatives, Longworth House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for H.R. 2482, the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

RUDOLPH G. PENNER, *Director.*

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 2482.

2. Bill title: Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

3. Bill status: As ordered reported by the House Committee on Agriculture, June 18, 1986.

4. Bill purpose: H.R. 2482 would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by changing numerous procedures used by the Environmental Protection Agency (EPA) to register pesticides, including those related to data gathering, cancellation and enforcement. The bill would mandate a comprehensive process to be used in reregistering substances that had been approved under earlier versions of the act. H.R. 2482 would also

provide for greater public and state access to pesticide data at various stages of the registration process.

H.R. 2482 would authorize appropriations for fiscal years 1987 through 1991 for abatement and control programs carried out under the act and for pesticide research. The bill would authorize separate appropriations of sums necessary to cover 50 percent of the cost to states or Indian tribes of training programs and pesticide certification and licensing. An additional $500,000 a year would be authorized for the development of a computerized data retrieval system as required by Title VI.

Title III of the bill would provide for reregistration fees to be collected from pesticide registrants when applications and supporting data are submitted. Amounts generated through fees would be deposited into a revolving fund for use by the EPA in carrying out the reregistration program.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1987	1988	1989	1990	1991
Estimated authorization level	88	97	101	108	116
Estimated outlays	59	85	97	105	113

The costs of this bill fall within budget function 300.

The table does not include any costs that may be incurred as a result of legal actions arising out of the EPA's disclosure of data to a state. Under Section 601 of the bill, such actions may arise if a state improperly uses data obtained from the EPA. In such situations, defined by the bill to involve a taking of property, all state actions shall be deemed to be actions of the federal government. As in any situation involving potential costs to satisfy legal claims that may or may not arise in the future, it is not possible to estimate the likely budgetary impact of Title VI. However, if successful claims do arise, the cost to the federal government could be significant.

Basis of estimate: For the purpose of this estimate, it is assumed that the full amounts authorized will be appropriated for each fiscal year.

Authorization levels for 50 percent matching grants to states and Indian tribes have been estimated on the basis of information obtained from the EPA. The total cost to the states of carrying out training and certification/licensing activities required under the act, as amended by Title XVI of this bill, is estimated to be about $18 million a year. If the EPA is to be able to enter into cooperative agreements specifying a federal/state cost share of 50/50, approximately $9 million would have to be appropriated each year. Currently, about $2.5 million per year is appropriated for these grants.

Outlays for pesticide programs, grants, and data systems development have been estimated on the basis of historical spending patterns for similar activities.

6. Financing mechanism: Most of the programs authorized by this bill would be funded through authorizations that would be sub-

ject to subsequent appropriation acts. However, Title III of the bill would create direct spending of an estimated $5 million a year. This direct spending would occur through a revolving fund and would be funded through offsetting collection that the EPA would be required to collect from reregistration applicants. CBO estimates that these collections would total about $45 million over nine years, or $5 million a year through fiscal year 1995.

7. Estimated cost to State and local governments: Title XII would impose new requirements on states relating to their training and certification/licensing programs. Under current law, states spend at least $5 million per year on these activities, about $2.5 million of which is recovered through federal matching grants. The requirements in Title XII are expected to result in additional costs to states of about $13 million, one-half of which would be recovered through federal matching grants, assuming appropriation of the necessary sums.

8. Estimate comparison: None.

9. Previous CBO estimate: None.

10. Estimate prepared by: Deb Reis.

11. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2 (l)(4) of Rule XI of the Rules of the House of Representatives, the Committee estimates that enactment of H.R. 2482, as amended, will have no inflationary impact on the national economy.

OVERSIGHT STATEMENT

No summary of oversight findings and recommendations made by the Committee on Government Operations under clause 2(b)(2) of Rule X of the Rules of the House of Representatives was available to the Committee with reference to the subject matter specifically addressed by H.R. 2482, as amended.

No specific oversight activities other than the hearings detailed in this report were conducted by the Committee within the definition of clause 2(b)(1) of Rule X of the Rules of the House of Representatives.

SUPPLEMENTAL VIEWS TO ACCOMPANY H.R. 2482

During consideration of this bill by the House Agriculture Committee, an amendment was offered, and later withdrawn, which would affect the ability of the states to act on pesticide residue tolerance levels on foods. This amendment would have caused a number of difficulties in the current authorities of states under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and under the Federal Food, Drug, and Cosmetics Act (FFDCA).

First, the amendment would improperly preempt a state's authority to limit pesticide contamination in the food chain in order to protect the health of it citizens. For decades states have had the authority to establish pesticide residue tolerances under the FFDCA, and arguments about marketing convenience do not justify depriving them of this basic right. As with other areas of pesticide regulation, federal tolerances should be used as mandatory minimum standards, but a state should have the option of adopting a stricter standard of protection for its citizens if it sees fit. In addition, states need the flexibility to protect subgroups within their populations whose dietary habits might expose them to a level of pesticide not anticipated by the federal standard.

Second, this amendment is unnecessary. Though states have long been able to set and enforce tolerances within their borders, they have exercised this authority only rarely. The experience with two pesticides—ethylene dibromide (EDB) and daminozide—demonstrate that state-established tolerances are the exception rather than the rule.

In 1984, several states established separate tolerances for EDB, a soil fumigant and a fumigant for citrus, stored grain, and other food products. These state actions were prompted by the inability of the federal government to establish a tolerance level for EDB due to a dysfunction between FIFRA and FFDCA for a period after the discovery of adverse health effects. Left without a binding legal standard for residues, the states were left on their own to act until federal law could catch up with the explosive situation.

This year, Maine and Massachusetts have taken steps to establish state tolerances for daminozide, a growth regulator used primarily on apples and peanuts. Again, state actions have been prompted by delays at the federal level in setting a safe tolerance level when evidence indicated one was needed. In September 1985, EPA announced plans to cancel registrations of daminozide because of data showing it to be a carcinogen. But in January 1986, the agency reversed that decision and decided to ask for further data which will not be submitted until 1988. The agency is convinced that the chemical is a carcinogen but needs further data to quantify that risk. The states were persuaded to act based upon the existing data and decided not to wait for the federal government.

The record of state tolerance-setting shows a clear pattern of responsible action. States should be free to act swiftly and responsibly when the federal regulatory apparatus is unable to react. There is nothing in the history of this issue to suggest that a state has acted to willfully obstruct commerce. Rather, the actions have been taken in the light of clear risk when the federal government has been unable, under federal law, to take the responsible action.

Third, an amendment of this nature would not have been suited to reauthorization of FIFRA, since it deals with provisions and authorities of the FFDCA. Such an amendment could have jeopardized the passage of the carefully crafted compromise represented in H.R. 2482, as reported by drawing unneeded controversy into the bill. Such an amendment also raises jurisdictional concerns since the FFDCA is under another Committee's jurisdiction.

Lastly, adoption of the amendment by the Committee could have created problems with the administration of FIFRA and FFDCA. The amendment as offered prohibited states from establishing permissible levels for pesticide residues if the federal government has already established a level either formally, by rule, or through such informal mechanisms as speeches, press releases, or letters. Thus, states could have been required to abide by federal decisions without the protections of due process and public comment. Also, the language in the amendment would have imposed an unreasonably high standard for the states to meet in order to sucessfully petition for a different state tolerance level based upon "imminent hazard."

The withdrawal of the amendment in Committee was a good decision. If this amendment is offered during consideration of H.R. 2482 on the House floor, its defeat would be an even better decision.

GEORGE E. BROWN, Jr.
JIM WEAVER.
LANE EVANS.

SUPPLEMENTAL VIEWS OF HON. PAT ROBERTS, HON. ED MADIGAN, HON. STEVE GUNDERSON, AND HON. SID MORRISON

We commend all of the parties involved in the effort that has led to the Agriculture Committee passing this bill.

However, we believe there are several issues in this bill that were not addressed adequately or in some cases not addressed at all. The first area of concern is the reregistration fee. The bill calls for the EPA to reregister the 600 active ingredients that do not have adequate data on file. The bill also places specific deadlines on the agency and to help the agency accomplish this task provides for a $150,000 reregistration fee to be paid by the registrant of the active ingredient.

We have concern over the concept of user fees. As with most areas of regulation, the industry or individual seldom asks for the burden of regulation. Instead, the Committee decided that it was in the public interest to impose regulation upon that industry. If it is in the public interest to regulate the sale and use of pesticides, then that cost should be borne by the public at large not through user fees that will be passed on, in this case, to the farmer-stockman.

We are well aware of the budget restrictions that we face within our many regulatory agencies. This bill contains numerous demands on the Office of Pesticide Programs that will be nearly impossible for it to meet, even with the reregistration fees provided for in this bill.

In fact, the Agency estimates that the shortfall will be nearly $50 million over the reregistration period. So once again the mandate is that an agency do its job, without providing adequate resources for it to do the job. The shortfall in resources will surely mean that the Office of Pesticide Programs will not meet the mandated deadlines in this bill.

And the missing of deadlines is subject to judicial review. While this bill does not specifically permit attorneys' fees for deadline suits against the EPA, the Equal Access to Justice Act does, and FIFRA is one of the statutes referenced in that Act. This means, as the bill was reported out of committee, the Office of Pesticide Programs is partially funded by user fees and that attorneys' fees for deadline suits will come out of the agency budget. We believe this is a counter-productive use of user fees, especially when the deadline suits often accomplish nothing more than the courts agreeing that the agency has missed the deadline.

Another issue of considerable importance to agriculture that was not addressed in the bill, is the issue of uniform pesticide residue tolerances. Once a chemical has complete data on file at the EPA, been cleared by the Food and Drug Administration, and a tolerance for residues has been established at the Federal level it makes

little sense for states to establish different tolerances that have and will create substantial problems in interstate commerce and the farmer-stockman.

During Committee consideration, the Committee failed to include the Stenholm-Roberts amendment for uniform tolerances, because of jursidictional concerns, but only after the Committee on a recorded vote of 31 yeas and 9 nays voted in favor of the amendment. The amendment is a very modest solution to the problems created by states establishing tolerances different from the Federal level. The amendment would require that once a chemical has gone through the reregistration process outlined in this bill or been registered after April 25, 1986 (this date was picked because this is the date that EPA issued the complete registration standards for a chemical) and that a tolerance has been established, that tolerance would be uniform throughout the nation. However, as a safeguard for the states they would be allowed to petition the Federal government to adopt a different tolerance.

The final concern we have with this bill, is a problem that we have had in recent years with many environmental statutes. This bill for the most part is regulation that is being put into the statute. Congress should be in the business of writing laws that give general direction to the Executive branch and not spelling out in minute detail how the Executive branch is to carry out that law. It is our prediction that this legislation may well come back to haunt us to the detriment of all concerned. The Executive branch should have flexibility in carrying out the statutes we write.

PAT ROBERTS.
ED MADIGAN.
STEVE GUNDERSON.
SID MORRISON.

DISSENTING VIEWS OF HON. RON MARLENEE

I commend the tireless efforts of my colleagues and friends on the Agriculture Committee which are reflected in H.R. 2482. The compromises contained in this bill were reached only after hours of negotiation and represent the views of many individuals. However, I voted against reporting the bill out of Committee for two reasons. first, I question the need for this greatly expanded version of FIFRA. Montana has a great many farmers and ranchers affected by this bill, and producers who have contacted me are reluctant, in view of their experience with the Environmental Protection Agency and the federal government in general, to see the additional authority created in those bodies.

Second, I believe that the Committee as a whole failed to establish the sound economic footing necessary for the implementation of the new and expanded regulatory requirements in this bill—in particular re-registration. The bill sets some 1,100 deadlines for EPA in this section. It also authorizes lawsuits to enforce these deadlines. The Committee has been told repeatedly that the monies authorized to be appropriated and recovered through fees on registrants are at least $48 million short. This is approximately 25% of the entire program. Until that financial problem is cured—either by appropriating the necessary additional funds or refining the focus of the program—EPA can be expected to miss deadlines—and lawsuits to force EPA to act can be expected.

Such "deadline" suits have become very popular over the past few years with certain plaintiffs. The plaintiff always wins; the result is that a new schedule embodied in a court decree is negotiated for EPA action, and, at least in theory, the public benefits because the lawsuit forces the agency to act. But in fact, the new schedule set is the one that the court finds reasonable, based on EPA's available resources and competing priorities—the one EPA had set for itself anyway.

The problem with these lawsuits is that the taxpayer picks up the tab for the attorneys' fees, which can be substantial. The average cost in attorneys' fees of such deadline suits is about $50,000. The attorneys' fee cost of the potential 1,100 deadline suits in the re-registration section would therefore be $55 million. Where as in FIFRA, there is no specific attorney's fee provision in the statute, fees are awarded under the Equal Access to the Justice Act. Under a 1985 amendment to that Act these fees are paid *out of EPA's* budget, thereby reducing the money available to the agency to carry out its regulatory tasks.

I believe this potential diversion of EPA program funds is wrong, as do 18 other members of the Committee who voted with me to prohibit the award of attorneys' fees for deadline suits in the re-registration program. It is especially wrong in the re-registration program because the bill, for the first time under FIFRA, requires

registrants to pay fees to EPA to review and re-register their products. It offends common sense and public policy to assess registrant fees to enable EPA to review data ($150,000/registrant) while simultaneously creating a litigation system to pass millions of taxpayer dollars through EPA's budget into the hands of outside interest groups in the form of attorneys' fees.

The purpose of deadlines is to increase EPA accountability for the discharge of tasks Congress requires it to perform. That accountability should be pursued and required through Congressional oversight and the provision of adequate resources to the agency, not through litigation.

It is my view, therefore, that at a minimum Congress should prohibit the award of any attorneys' fees in a suit brought to enforce the deadlines in the re-registration section.

RON MARLENEE.

APPENDIX

The committee amendment to the bill is as follows:

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986".

(b) TABLE OF CONTENTS.—The table of contents is as follows:

Sec. 1. Short title and table of contents.
Sec. 2. References to the Federal Insecticide, Fungicide, and Rodenticide Act.

TITLE I—REGISTRATION

Sec. 101. Preregistration access to data.
Sec. 102. Criminal penalties for disclosure of information.
Sec. 103. Conditional registration.
Sec. 104. Definition of outstanding data requirement.
Sec. 105. Reregistration of registered pesticides.
Sec. 106. Administrator's authority to require data on inert ingredients.
Sec. 107. Definition of ingredient statement.
Sec. 108. Disclosure of inert ingredients.
Sec. 109. Compensation for data on inert ingredients.

TITLE II—INFORMATION DISCLOSURE

Sec. 201. Public right to know.
Sec. 202. Data disclosure to States.

TITLE III—REVIEW AND CANCELLATION

Sec. 301. Public interim administrative review.
Sec. 302. Proceedings under section 6.
Sec. 303. Cancellation and change in classification or labels.
Sec. 304. Public hearings and scientific review.
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TITLE X—EFFECTIVE DATE

Sec. 1001. Effective date.

SEC. 2. REFERENCES TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.

Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

TITLE I—REGISTRATION

SEC. 101. PREREGISTRATION ACCESS TO DATA.

(a) IN GENERAL.—Section 3(c) (7 U.S.C. 136a(c)) is amended by adding at the end thereof the following new paragraph:

"(9) PREREGISTRATION ACCESS TO DATA.—

"(A) If an application for—

"(i) a registration of a pesticide containing a new active ingredient, or

"(ii) a registration of a pesticide to authorize the initial food use of a pesticide active ingredient,

is submitted to the Administrator, the Administrator, before acting on such application, shall provide, in accordance with this paragraph, public access to health, safety,

and environmental data that are submitted or cited in support of such application.

"(B) To obtain access to the data referred to in subparagraph (A), a person shall send by certified mail—

"(i) not later than 30 days after the publication under paragraph (4) of a notice of the application referred to in subparagraph (A), and

"(ii) simultaneously to the Administrator and to the applicant for the registration of the pesticide,

a request for such access and the affirmation required by subparagraph (D).

"(C)(i) Unless within 15 days after the Administrator's receipt of a request for access to such data and of an affirmation complying with subparagraph (D) the applicant submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and the reasons for the objection, the Administrator shall grant the request. If an objection to a request is submitted to the Administrator within such 15-day period, the Administrator shall determine whether to grant the request within 5 days after the receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the applicant making the objection has been notified that access has been granted.

"(ii) If access to data is denied under clause (i), comments on the application for which such data were submitted or cited shall be filed within 60 days after the decision of the Administrator denying access.

"(D)(i) Data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) containing the information prescribed by clause (ii).

"(ii) The affirmation required under clause (i) shall—

"(I) state that the person is not engaged in, and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate thereof engaged in, the production, sale, or distribution of a pesticide,

"(II) identify any business, employer, or other person, if any, on whose behalf the person is requesting access to the data, and

"(III) state that the person will not intentionally or recklessly violate this paragraph.

For purposes of this clause, an affiliate of a person is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the other person.

"(iii) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

"(E)(i) Data supporting an application may be made available under subparagraph (A) to a person only for the purpose of permitting the person to comment to the Administrator on such application. Such comments may rea-

sonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

"(ii) Except as provided in clause (iii), a person who obtains data under subparagraph (A) (directly or indirectly) may not—

"(I) publish, copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world, or

"(II) use the data for any purpose in any court or agency of the United States or any State or political subdivision thereof before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

"(iii) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide for which such data were submitted.

"(F)(i) Data made available under this paragraph may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by this paragraph and may not be removed from such office.

"(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent to the data submitter on request.

"(G) Once access to data respecting an application is granted, the data may be examined and notes may be taken for use in developing comments on the application. Such comments on the application shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator for an additional 30 days for good cause.".

(b) NOTICE OF APPLICATION.—Section 3(c)(4) (7 U.S.C. 136a(c)(4)) is amended—

(1) in the first sentence, by striking out "promptly" and inserting in lieu thereof "not later than 30 days", and

(2) in the second sentence—

(A) by striking out "The notice" and inserting in lieu thereof "Except as provided in paragraph (9), the notice", and

(B) by striking out "30" and inserting in lieu thereof "60".

SEC. 102. CRIMINAL PENALTIES FOR DISCLOSURE OF INFORMATION.

Paragraph (3) of section 14(b) (7 U.S.C. 136l(b)(3)) is amended to read as follows:

"(3) DISCLOSURE OF INFORMATION.—

"(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product ac-

quired under section 3 shall be fined not more than $25,000, or imprisoned for not more than 3 years, or both.

"(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

"(i) is granted access to data under section 3(c)(9), and

"(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

"(I) knowingly violates such section, or

"(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000, or imprisoned for not more than 3 years, or both.".

SEC. 103. CONDITIONAL REGISTRATION.

Subparagraphs (B) and (C) of section 3(c)(7) (7 U.S.C. 136a(c)(7)) are amended to read as follows:

"(B)(i) The Administrator may conditionally amend the registration of a pesticide under this subparagraph to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

"(I) the applicant has submitted or cited the additional data that the Administrator may require solely for the proposed additional use,

"(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment, and

"(III) the additional use is in the public interest.

"(ii)(I) Except as provided in subclause (II), if the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), no registration of the pesticide may be amended under clause (i) to add any food or feed use during the pendency of any evaluation by the Administrator initiated by such notice.

"(II) If the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), the Administrator may amend the registration of the pesticide under clause (i) to add a minor food or feed use if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is not available an effective alternative pesticide that does not meet or exceed such risk criteria.

"(iii) An applicant seeking an amended registration of a pesticide under this subparagraph shall submit or cite to the Administrator such data as would be required to obtain a registration of a similar pesticide under para-

graph (5). Except as provided in clause (iv), if the applicant is unable to submit or cite an item of such data because it has not yet been generated, the Administrator may amend the registration of the pesticide under such conditions as will require the submission or citation of such data not later than the time such data are required to be submitted for the maintenance of a registration of the similar pesticide under this section.

"(iv) If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide and if a period reasonably sufficient for the generation and submission of such data has elapsed since the Administrator first imposed the data requirement, a conditional amendment to permit an additional use of the pesticide for other than a minor use shall not be granted under clause (i) unless such data have been submitted.

"(C)(i) The Administrator may conditionally register a pesticide under this subparagraph containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data that have not been submitted because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement (I) on the conditions that by the end of such period the Administrator receives such data and that the data that the Administrator receives do not meet or exceed risk criteria enumerated in regulations issued under paragraph (8), and (II) on such other conditions as the Administrator may prescribe.

"(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

"(I) use of the pesticide during the period referred to in clause (i) will not cause any unreasonable adverse effect on the environment, and

"(II) use of the pesticide is in the public interest.

"(iii) The Administrator shall not conditionally register a pesticide under this subparagraph if data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of such a pesticide under paragraph (5), a period reasonably sufficient for generation of such data has elapsed since the Administrator first imposed the data requirement, and such data have not been submitted to the Administrator.".

SEC. 104. DEFINITION OF OUTSTANDING DATA REQUIREMENT.

Section 2 (7 U.S.C. 136) is amended by adding at the end the following new subsection:

"(ff) OUTSTANDING DATA REQUIREMENT.—

"(1) IN GENERAL.—The term 'outstanding data requirement' means a requirement for any study, information, or data which

is necessary to make a determination under section 3(c)(5) and which study, information, or data—

"(A) has not been submitted to the Administrator, or

"(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 3(c)(5) and the regulations and guidelines issued thereunder, as determined by the Administrator.

"(2) FACTORS.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.".

SEC. 105. REREGISTRATION OF REGISTERED PESTICIDES.

(a) AMENDMENT.—The Act is amended by inserting after section 3 (7 U.S.C. 136a) the following new section:

"SEC. 3A. REREGISTRATION OF REGISTERED PESTICIDES.

"(a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

"(1) there are no outstanding data requirements, and

"(2) the requirements of section 3(c)(5) have been satisfied.

"(b) SPECIAL AUTHORITIES OF ADMINISTRATOR.—

"(1) GUIDELINES.—Not later than one year after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator, by order, shall issue guidelines to be followed by registrants in—

"(A) summarizing studies,

"(B) reformatting studies,

"(C) identifying adverse information, and

"(D) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section,

in accordance with subsection (f)(1). Guidelines issued under this paragraph shall not be subject to judicial review.

"(2) MONITORING.—The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under this section.

"(3) SUSPENSIONS AND PENALTIES.—

"(A) The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if—

"(i) the Administrator determines that progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under subsection (e)(3)(B) or (f)(1)(H) within the time period prescribed by subsection (e)(4)(B) or (f)(2)(B) or

the registrant has not submitted such data to the Administrator within such time period,

"(ii) the Administrator determines that tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under subsection (g)(1)(B),

"(iii) the Administrator determines that progress is insufficient to ensure submission of the data referred to in clause (ii) within the time period prescribed by subsection (g)(2)(B) or the required data have not been submitted to the Administrator within such time period, or

"(iv) a registrant fails to comply with clause (ii) or (iii) of section 3(c)(2)(B).

"(B) A registrant who submits a certification under subsection (f)(1)(G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

"(c) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

"(1) The first phase shall include the listing under subsection (d) of the active ingredients of the pesticides that will be reregistered.

"(2) The second phase shall include the submission to the Administrator under subsection (e) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

"(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (f).

"(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (g) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

"(5) The fifth phase shall include the review by the Administrator under subsection (h) of data submitted for reregistration and appropriate regulatory action by the Administrator.

"(d) PHASE ONE.—

"(1) PRIORITY FOR REREGISTRATION.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986) that—

"(A) are in use on or in food or feed and may result in postharvest residues,

"(B) may result in residues of potential toxicological concern in potable groundwater, edible fish, or shellfish,

"(C) have been determined by the Administrator before the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 to have significant outstanding data requirements, or

"(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

"(2) REREGISTRATION LISTS.—For purposes of reregistration under this section, the Administrator shall by order—

"(A) not later than 70 days after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list pesticide active ingredients for which registration standards have been issued before such date,

"(B) not later than 4 months after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list the first 150 pesticide active ingredients, as determined under paragraph (1),

"(C) not later than 7 months after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list the second 150 pesticide active ingredients, as determined under paragraph (1), and

"(D) not later than 10 months after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

"(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

"(4) NOTICE TO REGISTRANTS.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (e) whether they intend to seek or not to seek reregistration of such pesticides.

"(e) PHASE TWO.—

"(1) IN GENERAL.—The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

"(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

"(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

"(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide,

the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

"(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

"(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

"(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient,

"(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations, and

"(iii) data identified under clause (i) that have not been submitted to the Administrator, and

"(B) either—

"(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B), or

"(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (f)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

"(4) TIME PERIODS.—

"(A) A submission under paragraph (2) or (3) shall be made—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient,

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient, and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later

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than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

"(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(5) CANCELLATION AND REMOVAL.—

"(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

"(B) If no registrant of a pesticide containing an active ingredient listed under subsection (d)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient, if no such registrant complies with paragraph (3)(A), or if no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A), or if the fee prescribed by subsection (j)(1) has not been paid with regard to the active ingredient, the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (d)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice. After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

"(i) during the comment period a person acquires the registrant's rights in that registration,

"(ii) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2), and

"(iii) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by subsection (j)(1) has been paid.

"(f) PHASE THREE.—

"(1) INFORMATION ABOUT STUDIES.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) who has submitted a notice under subsection (e)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under subsection (b)(1), to the Administrator—

"(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section,

"(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations,

"(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982,

"(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section,

"(E) an identification of data that are required to be submitted to the Administrator under section 6(g)(4) indicating an adverse effect of the pesticide,

"(F) an identification of any other information available that in the registrant's view supports the registration,

"(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B),

"(H) either—

"(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant, or

"(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an

offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing, and

"(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

"(2) TIME PERIODS.—

"(A) The information required by paragraph (1) shall be submitted to the Administrator—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient,

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient, and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

"(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, upon application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(3) CANCELLATION.—

"(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

"(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

"(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

"(iii) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice

shall be sent to the registrant by certified mail. The registration shall be cancelled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant. If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

"(g) PHASE FOUR.—

"(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQUIREMENTS.—

"(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (e)(3) and (f)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the Administrator's review under this section, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (f)(1).

"(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

"(2) TIME PERIODS.—

"(A) The Administrator shall take the action required by paragraph (1)—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 18 months after the date of the listing of such active ingredient,

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 24 months after the date of the listing of such active ingredient, and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

"(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circum-

stances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(h) PHASE FIVE.—

"(1) DATA REVIEW.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (d)(2) and of all other available data found by the Administrator to be relevant.

"(2) REREGISTRATION AND OTHER ACTIONS.—

"(A) ELIGIBILITY FOR REREGISTRATION.—Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (g), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year.

"(B) PRODUCT-SPECIFIC DATA.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission. The Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

"(C) REREGISTRATION.—After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

"(D) OTHER ACTION.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

"(i) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (e), (f), (g), or (h) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

"(j) FEES.—

"(1) INITIAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of

subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $50,000 on submission of information under paragraphs (2) and (3) of subsection (e) for such ingredient.

"(2) FINAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—

"(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000 (i) on submission of information for such ingredient under subsection (f)(1) if data are reformatted under subsection (f)(1)(C), or (ii) on submission of data for such ingredient under subsection (f)(2)(B) if data are not reformatted under subsection (f)(1)(C).

"(B) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (A) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000 at such time as the Administrator shall prescribe.

"(3) FEES FOR OTHER PESTICIDE ACTIVE INGREDIENTS.—

"(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is not an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

"(B) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (A) of subsection (d)(2) and that is not an active ingredient of any pesticide that is registered for a major use on food or feed shall collectively pay a fee of not more than $100,000 and not less than $50,000 at such time as the Administrator shall prescribe.

"(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.—

"(A) In the case of an active ingredient of a pesticide that is registered solely for an agricultural or nonagricultural minor use or in the case of a pesticide the value or volume of use of which is small, the Administrator, upon application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

"(B) In the case of an antimicrobial active ingredient for which the production level does not exceed 1,000,000 pounds per year, the Administrator, upon application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

"(C) In the case of a small business registrant that produces an active ingredient of a pesticide, the Administra-

tor, upon application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3). For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

"(i) has 125 or fewer employees, and

"(ii) for the last 3 years before application is made for a reduction or waiver had an average annual gross revenue that did not exceed $20,000,000.

"(5) OTHER FEES.—On payment of fees for the reregistration of a pesticide in accordance with paragraph (1), (2), (3), or (4), the Administrator may not levy any other fees for the reregistration with respect to that active ingredient.

"(6) APPORTIONMENT.—If two or more registrants are required to pay any fee prescribed by this subsection with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the three calendar years preceding the date of payment of such fee. The Administrator, by order, may require such registrants to submit such reports as the Administrator determines to be necessary to allow the Administrator to apportion fees under this paragraph. If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any fee prescribed by this subsection for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under paragraph (1), (2), or (3)(B), the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator then shall reapportion the fee among the remaining registrants and notify such registrants that they are required to pay to the Administrator any unpaid balance of the fee within 30 days after receipt of such notice.

"(k) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (e), (f), (g), and (j) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

"(l) REREGISTRATION FUND.—

"(1) There shall be established in the Treasury of the United States a reregistration fund.

"(2) All fees collected by the Administrator under subsection (j) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out this section.

"(3) Money in the fund not currently needed to carry out this section shall be—

"(A) maintained on hand or on deposit,

"(B) invested in obligations of the United States or guaranteed thereby, or

"(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(4) The Administrator shall—

"(A) provide an annual accounting of the fees collected and disbursed from the fund, and

"(B) take all steps necessary to ensure that expenditures of such funds are used only to carry out this section.

"(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).".

(b) TECHNICAL AMENDMENT.—Subsection (g) of section 3 (7 U.S.C. 136a(g)) is repealed.

(c) DEFINITION.—

(1) Section 2 (7 U.S.C. 136) (as amended by section 104) is amended by adding at the end the following:

"(gg) ANTIMICROBIAL.—The term 'antimicrobial' means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

"(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air,

"(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture,

"(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects, or

"(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces.".

(2) Section 2(u) (7 U.S.C. 136(u)) is amended by striking out "and" immediately before the first clause (2), by adding ", and" at the end of the first clause (2), and by adding a new clause (3) as follows: "(3) any substance or mixture of substances intended for a purpose described in subsection (gg)".

SEC. 106. ADMINISTRATOR'S AUTHORITY TO REQUIRE DATA ON INERT INGREDIENTS.

(a) SECTION 3(c)(2)(A).—Subsection (c)(2)(A) of section 3 (7 U.S.C. 136a(c)(2)(A)) is amended by inserting after "any additional kind of information under subparagraph (B) of this paragraph" the following: "including information regarding an inert ingredient in a pesticide".

(b) PRIORITY LIST AND DATA REQUIREMENTS.—Section 3 (7 U.S.C. 136a) is amended by adding at the end thereof the following new subsection:

"(g) PRIORITY LIST AND DATA REQUIREMENTS FOR INERT INGREDIENTS.—

"(1) ESTABLISHMENT OF LIST.—Subject to paragraph (4), the Administrator shall establish a priority list of inert ingredients consisting of—

"(A) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8),

"(B) inert ingredients (i) for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, (ii) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect, and (iii) that have significant use in pesticides or to which there is significant exposure from pesticides, and

"(C) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment and to which there is significant exposure from pesticides.

"(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

"(3) JUDICIAL REVIEW.—The priority list under paragraph (1), the inclusion or exclusion of an ingredient on or from the priority list, and any revision of the priority list shall not be subject to judicial review.

"(4) NUMBER OF INGREDIENTS.—The priority list under paragraph (1) shall consist of not less than 50 inert ingredients unless the Administrator determines that there is not a sufficient number of inert ingredients meeting the requirements for listing under paragraph (1) to reach such minimum number. Such list may not exceed 75 inert ingredients.

"(5) ADDITIONAL DATA.—

"(A) The Administrator shall determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list under paragraph (1). The Administrator shall require submission of such data from each registrant of such pesticide under this Act or from manufacturers and processors of the inert ingredient under the Toxic Substances Control Act. Such data shall be submitted within a reasonable time but not later than 4 years after the date of the request. The Administrator may extend the period for the submission of data by not more than 2 years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the necessary data.

"(B) Data requirements imposed under subparagraph (A) or a decision not to require data for an inert ingredient shall be subject to judicial review under section 16(b).

"(6) EVALUATION.—Within 1 year after the receipt of additional data under paragraph (5) for an inert ingredient, the Administrator shall evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment caused by pesticides containing such inert ingredient. Under exceptional circumstances, the Administrator may extend the period for evaluation by not more than 1 year.

"(7) CONSTRUCTION.—This subsection shall not be construed to affect the authority of the Administrator—

"(A) to regulate under this Act impurities, contaminants, degradants, or other ingredients of pesticides that have not been deliberately added to the pesticides,

"(B) to regulate under this Act any deliberately added inert ingredient that has not previously been used in a pesticide or a significant new use in a pesticide of a deliberately added inert ingredient,

"(C) to require the submission of short-term, environmental fate, or residue studies for deliberately added inert ingredients, or

"(D) to require the submission of revised formula statements under subsection (c)(2)(B).".

(c) DATA COMPENSATION.—Section 3(c)(1)(D)(ii) (7 U.S.C. 136a(c)(1)(D)(ii)) is amended—

(1) by striking out "or for reregistration" and inserting in lieu thereof "for reregistration, or to support the safety of an inert ingredient", and

(2) by inserting "or in support of the safety of an inert ingredient" before "by any other person".

SEC. 107. DEFINITION OF INGREDIENT STATEMENT.

Subsection (n) of section 2 (7 U.S.C. 136(n)) is amended to read as follows:

"(n) INGREDIENT STATEMENT.—The term 'ingredient statement' means a statement that contains—

"(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in a pesticide,

"(2) the name of each inert ingredient in the pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the use pattern and concentration level of the inert ingredient in the pesticide,

"(3) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic,

"(4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented, and

"(5) the name of any inert ingredient for which the Administrator has required additional data under section 3(g)(5) because such ingredient is listed under section 3(g)(1)(A) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8).".

SEC. 108. DISCLOSURE OF INERT INGREDIENTS.

Section 10(d) (7 U.S.C. 136h(d)) is amended in the first sentence of paragraph (3) by striking out "If" and inserting in lieu thereof "Except with respect to disclosure of information on inert ingredients in ingredient statements in accordance with section 2(n), if".

SEC. 109. COMPENSATION FOR DATA ON INERT INGREDIENTS.

Subparagraph (D) of section 3(c)(2) (7 U.S.C. 136a(c)(2)) is amended to read as follows:

"(D) EXEMPTION.—

"(i) No applicant for registration or amended registration of a pesticide who proposes to purchase a registered pesticide from another producer to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

"(I) submit or cite data pertaining to such purchased pesticide, or

"(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data.

"(ii) No applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study concerning such ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.".

TITLE II—INFORMATION DISCLOSURE

SEC. 201. PUBLIC RIGHT TO KNOW.

(a) FACT SHEETS AND REPORTS.—Section 7 (7 U.S.C. 136e) is amended by adding at the end thereof the following new subsection:

"(e) PUBLIC RIGHT TO KNOW.—

"(1) Any producer operating an establishment in any State shall prepare or obtain a fact sheet complying with this subsection for each active ingredient manufactured or used at the establishment. The producer shall maintain copies of the fact sheet at the establishment and shall furnish a copy to any person on request.

"(2) Each fact sheet for an ingredient required under paragraph (1) shall—

"(A) contain the chemical name, each common name, and any trade name of the ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient, and

"(B) be revised as often as is necessary to reflect current information about the ingredient.

The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

"(3) Each producer to whom this subsection applies shall furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes—

"(A) for each establishment operated by the producer in any State, the name of each ingredient for which a fact sheet is required that is manufactured or used at that establishment, and

"(B) for each ingredient for which a fact sheet is required, the location of each establishment where such ingredient is manufactured or used by the producer, and

"(C) a current copy of each required fact sheet.

"(4) The fact sheets required by paragraph (1) and the annual reports required by paragraph (3) shall be available to the public.".

(b) CONFIDENTIAL INFORMATION.—Section 7(d) (7 U.S.C. 136e(d)) is amended by inserting "and production locations" after "names".

SEC. 202. DATA DISCLOSURE TO STATES.

(a) STATES.—Section 10 (7 U.S.C. 136h) is amended by adding at the end thereof the following new subsection:

"(h) DATA DISCLOSURE TO STATES.—

"(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

"(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

"(A) the disclosure or use of data or information provided by the Administrator under paragraph (1) to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property, and

"(B) the act of a State with respect to such data or information shall be considered an act of the United States.

"(3) REQUIRED DISCLOSURE.—The Administrator shall disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that—

"(A) the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section, and

"(B) the law of the State allows the submitter of the data or information to recover just compensation in a civil action against the State for losses resulting from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or this section.".

(b) DATA SYSTEM.—Section 31 (7 U.S.C. 136y) is redesignated as section 33 and the following new section is inserted after section 30:

"SEC. 31. COLLECTION, DISSEMINATION, AND USE OF DATA.

"(a) DATA SYSTEMS.—The Administrator shall establish, administer, and be responsible for the continuing activities of a committee within the Environmental Protection Agency that shall design, establish, and coordinate an efficient system, within such agency, for the collection, dissemination to other Federal departments and agencies or States, and use of the data submitted to the Adminis-

trator under this Act. The Administrator shall ensure the completion, within 36 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, of the design and implementation of the system and procedures required by this subsection. The agency committee so established shall solicit advice from data users outside the Federal Government through means of a permanent advisory committee that shall consist of representatives from private groups, State governments and organizations, and industry, and other representatives as may be appropriate.

"(b) DATA RETRIEVAL.—The Administrator, in consultation and cooperation with the Secretary of Agriculture and other heads of appropriate Federal and State departments and agencies, shall design, establish, and coordinate an efficient and effective system for the retrieval of pesticidal, toxicological, and other scientific data that could be useful to the Administrator in carrying out this Act. Systematized retrieval shall be developed for use by all Federal and State departments and agencies with responsibilities in the area of regulation or study of pesticides and their effect on man and the environment.

"(c) INDEX.—In designing and implementing the systems required by subsections (a) and (b), the Administrator shall index information by pesticide name, Chemical Abstracts Service registry number, establishment site, and submitter so that information can be retrieved in a timely and useful manner.

"(d) REPORT.—The Administrator, within 24 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, shall submit a report to Congress on the progress made in designing and implementing the systems for information management required by this section. The report shall address the handling of information submitted before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 as well as the procedures established to ensure that collection of information after such date will comply with this section.

"(e) CONFIDENTIALITY.—Dissemination of information and data collected under this section to any State shall be subject to section 10.

"(f) AUTHORIZATION.—There are authorized to be appropriated for fiscal years 1987, 1988, 1989, 1990, and 1991 such sums as may be necessary to carry out this section.".

TITLE III—REVIEW AND CANCELLATION

SEC. 301. PUBLIC INTERIM ADMINISTRATIVE REVIEW.

(a) SECTION 3(c)(8).—Paragraph (8) of section 3(c) (7 U.S.C. 136a(c)(8)) is amended to read as follows:

"(8) PUBLIC INTERIM ADMINISTRATIVE REVIEW PROCEEDINGS.—

"(A) IN GENERAL.—A public interim administrative review process to determine whether the use of a pesticide (including a category of pesticides) may cause unreasonable adverse effects on the environment shall be conducted in accordance with this paragraph.

"(B) CRITERIA FOR INITIATING A PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

"(i) Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

"(ii) Such criteria shall be established on the basis of levels of risk and may include consideration of currently available exposure data.

"(iii) Absence of exposure data shall not delay or preclude initiation of a public interim administrative review. The Administrator may decline to initiate a public interim administrative review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

"(C) REVIEW REQUIREMENT.—The Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of such pesticide required under this Act unless such public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

"(D) PREREVIEW NOTICE PROCEDURES.—

"(i) On receipt of information respecting a pesticide demonstrating that the criteria for initiating a public interim administrative review established under subparagraph (B) have been met, the Administrator shall immediately notify all registrants of such pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met.

"(ii) Not later than 30 days after receipt of a notice provided under clause (i), a registrant may respond to such notice.

"(iii) Not later than 60 days after the Administrator provided a notice under clause (i) concerning a pesticide, the Administrator shall determine whether a public interim administrative review of the pesticide shall be initiated.

"(E) NOTICE.—If the Administrator intends to initiate a public interim administrative review of a pesticide that is registered for agricultural uses, the Administrator shall notify the Secretary of Agriculture of the intention to initiate such review and the reasons therefor.

"(F) REVIEW PROCEDURE.—

"(i) Any public interim administrative review proceeding shall be initiated and conducted in accordance with regulations published by the Administrator. Such regulations shall provide that a public interim administrative review shall include—

"(I) a notice of initiation of the public interim administrative review and opportunity for public comment on such notice,

"(II) a notice of a preliminary determination and opportunity for public comment on such notice, and

"(III) a notice of a final determination,

except that such regulations may authorize the Administrator to combine or forgo any such notice.

"(ii) Any proposed determination of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at its next scheduled meeting for comment solely on relevant scientific issues. The public may submit comments to the Scientific Advisory Panel concerning such issues.

"(iii) The notice of the initiation of a public interim administrative review or the notice of a preliminary determination shall state the basis for such review or determination and include a request for any additional data needed and a bibliography of all scientific data and studies and expert analyses concerning the risks or benefits of the pesticide that are under review. Information in the bibliography shall be made available to the public consistent with the requirements of section 10. The Administrator shall determine, to the extent feasible, before the initiation of the public interim administrative review which data in the bibliography may be disclosed to the public under section 10(d)(1). If the Administrator receives additional data concerning such risks or benefits, the Administrator, within 30 days after receiving the additional data, shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

"(iv) Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments may be submitted on such review or determination. Any person who submits comments shall disclose to the Administrator all scientific data and studies and expert analyses in such person's possession concerning the risks or benefits of the pesticide that are under review that were not included in the bibliography included in such notice. If such person receives additional scientific data or studies or expert analyses of such data or studies that were not included in such bibliography, the person shall disclose such scientific data, studies, and expert analysis to the Administrator within 30 days after receipt.

"(v) Not later than 18 months after the initiation of a review, the Administrator shall decide which regulatory action (if any) to take regarding the pesticide that is the subject of the review and shall publish the decision.

"(vi) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

"(I) additional data critical to a fair and accurate determination of risks posed by the pesticide subject to review are required,

"(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year, and

"(III) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for such data at such time.

"(G) JUDICIAL REVIEW.—Any person may seek judicial review under section 16(a) of the failure of the Administrator to act within the time period prescribed under this paragraph.".

(b) SCIENTIFIC ADVISORY PANEL.—The first sentence of section 25(d) (7 U.S.C. 136w(d)) is amended by striking out "The" and inserting in lieu thereof "Except with respect to a referral under section 3(c)(8)(F), the".

(c) APPLICATION OF AMENDMENTS.—The amendments made by this section shall apply to public interim administrative reviews under section 3(c)(8) of the Federal Insecticide, Fungicide, and Rodenticide Act initiated after January 1, 1987.

SEC. 302. PROCEEDINGS UNDER SECTION 6.

Section 6 (7 U.S.C 136d) is amended by redesignating subsection (f) as subsection (i) and by inserting after subsection (e) the following:

"(f) HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

"(1) GENERAL RULE.—Subsection (d), as modified by the special rules of paragraphs (2) and (3) of this subsection, shall govern any hearing under subsection (d) that results from the Administrator's final determination in a public interim administrative review proceeding under section 3(c)(8) that is initiated after January 1, 1987, that includes an opportunity for comment on a notice of preliminary determination issued in connection with such review, and for which the time between the first public notice for such review under section 3(c)(8)(F) and the close of the last comment period provided for such review is not less than 180 days.

"(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in such pesticide) following a public interim administrative review described by paragraph (1) may request, or intervene in, a hearing in the manner provided by subsection (b)(2)(B) within 30 days after such decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with section 3(c)(8)(F).

"(3) PROCEDURES.—

"(A) At the request of a party, the administrative law judge conducting the hearing may receive into evidence

portions of the public interim administrative review record and other evidence if the party demonstrates that such portions of the record and other evidence are relevant and material to the disputed issues and are not unduly repetitious and a competent witness is made available to be cross-examined on all matters relating to such evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the public interim administrative review proceeding by the exercise of due diligence by the offering party shall not be admissible.

"(B) The right of other parties to confront and cross-examine witnesses with respect to such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross-examination is not unduly repetitious.

"(C)(i) Not later than 120 days after the administrative law judge is appointed, prehearing matters shall be completed and the hearing shall commence.

"(ii) The administrative law judge may establish a schedule for prehearing matters, including discovery and motions, and shall ensure that the hearing schedule is met. The administrative law judge shall issue such orders as are appropriate for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision.

"(iii) Discovery shall be permitted after the expiration of 120 days after the appointment of the administrative law judge on a determination by the administrative law judge that (I) such discovery shall not in any way unreasonably delay the proceeding, (II) the information to be obtained is not otherwise obtainable, and (III) such information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

"(D) Any challenge to—

"(i) the authority to issue, or

"(ii) the procedural correctness of the issuance of,

any notice of intent to cancel or change classification or to any request for a hearing or motion to intervene shall be filed with the administrative law judge not later than 30 days before the commencement of the evidentiary phase of the hearing.

"(E) Not later than 30 days before the hearing commences, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits that the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended on motion by a party.

"(F) If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and when in the judgment of the administrative law judge it is necessary, may submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis under such time limits as may be established by the administrative law judge.

"(G) The administrative law judge shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that the schedule shall not prejudice the right of a party to present evidence. The person who requested a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

"(H) A hearing conducted in accordance with this subsection shall be completed and the Administrator shall make a final decision within 30 days after the issuance of the notice that gave rise to the hearing. The time limit imposed by this subparagraph may not be extended, except in exceptional circumstances in which such extension is essential for a fair and accurate determination of pivotal facts central to the proceeding. In no event may such time limit be extended more than 180 days. Any other time limit imposed by this paragraph may be extended for good cause.

"(I) Failure to complete a hearing and make a final decision within the time period prescribed by subparagraph (H) shall be grounds for a civil action in a district court of the United States seeking an order to establish a schedule requiring the prompt completion of the hearing, but shall not be grounds for termination of the hearing or for making a final decision respecting the pesticide that is the subject of the hearing.".

SEC. 303. CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.

Subsection (b) of section 6 (7 U.S.C. 136d(b)) is amended to read as follows:

"(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.—

"(1) NOTICE OF CANCELLATION OR CHANGE IN CLASSIFICATION.—

"(A) If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

"(i) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the action of the Administrator, or

"(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

"(B) A notice issued under subparagraph (A) shall be sent to each registrant of the pesticide with respect to which the notice is issued and shall be made public.

"(C) In determining whether to issue a notice under subparagraph (A), the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

"(D)(i) Not later than 60 days before sending a notice to a registrant or making public such notice under subparagraph (B), whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of the proposed notice under subparagraph (A) and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture shall provide comments on such notice and analysis to the Administrator within 30 days after receiving the copy of such notice.

"(ii)(I) If the Secretary of Agriculture provides such comments in writing within 30 days after receiving the copy of such notice, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

"(II) If the Secretary of Agriculture does not provide such comments in writing within 30 days after receiving the copy of such notice, the Administrator may notify the registrant and make public the notice at any time after such 30-day period.

"(iii) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary of Agriculture.

"(E) If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirements of notice to the Secretary of Agriculture prescribed by subparagraph (D) and submission to the Scientific Advisory Panel under section 25(d) and proceed in accordance with subsection (c).

"(2) HEARING.—

"(A) The action proposed in a notice issued under paragraph (1)(A) shall become final and effective at the end of 30 days after receipt by the registrant or publication of a notice issued under paragraph (1)(B), whichever occurs later, unless within that time—

"(i) the registrant makes the necessary corrections, if possible, or

"(ii) a request for a hearing is made by a person adversely affected by the notice.

"(B) Whenever a request for a hearing is made, the request shall—

"(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed, and

"(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

"(C) Any party to the proceeding may identify findings and conclusions in dispute.

"(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

"(E) On receipt of a request for a hearing from a person without an economic interest in the pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man or the environment.

"(3) FACTORS.—In taking any action under paragraph (1), the Administrator shall—

"(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restriction, and

"(B) consider the impact of such action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.

"(4) LABEL CHANGES.—

"(A) The Administrator may notify the registrant of a pesticide of a label change proposed by the Administrator that may be made by rulemaking under subparagraph (B) and provide that the registrant may submit comments to the Administrator on such proposed change in the 30-day period beginning on the date of the receipt of such notice. If a registrant who is notified by the Administrator of a proposed label change notifies the Administrator that the registrant does not object to such change, such change shall take effect as prescribed by the Administrator. If a registrant who is notified by the Administrator of a proposed label change does not submit comments to the Administrator in such 30-day period, the Administrator shall send such registrant a second notice stating that, if such registrant does not submit any comments to the Administrator in the 30-day period beginning on the date the registrant receives the second notice, the registration of such registrant shall be cancelled without a hearing or further notice. The registration of a registrant who does not submit comments on a second notice within such 30-day period shall be cancelled without a hearing or further notice. If in response to a notice under this subparagraph a registrant submits comments to the Administrator objecting to a proposed label change, the Administrator may proceed under subparagraph (B).

"(B) The Administrator may require changes to the label of a pesticide by informal rulemaking under this paragraph unless the changes—

"(i) are equivalent to a cancellation of a use,

"(ii) render the pesticide unmarketable, or

"(iii) otherwise have a major economic impact on persons affected by such changes.

If the Administrator may not require changes to the label of a pesticide by informal rulemaking under this paragraph because of clause (i), (ii), or (iii), the Administrator may only require such changes by a proceeding authorized by other provisions of this Act.

"(C) After the promulgation of a regulation under subparagraph (B), the Administrator shall notify each registrant of the pesticide subject to the regulation of the label change required by the regulation and provide a 30-day period for each registrant to apply to the Administrator for an amendment to the registration to comply with the regulation. If a registrant does not apply for such an amendment within such period, the Administrator shall issue a notice of intent to cancel the registration of such registrant in accordance with paragraph (2). For purposes of paragraph (2), such notice shall be deemed to have been issued under paragraph (1).

"(D) A registrant or user of a pesticide subject to a regulation issued under subparagraph (B) may request a hearing under subsection (d) on such regulation in accordance with paragraph (2). The scope of the hearing shall be limited to—

"(i) whether the pesticide complies with the regulation,

"(ii) whether the regulation by its terms is applicable to such pesticide, and

"(iii) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was promulgated, it would be unreasonable to require such pesticide to comply with the regulation.

"(E)(i) Except as provided in clause (ii), in an action under 16(e) for review of a regulation issued under subparagraph (B), the court, on request, shall postpone the effective date of the regulation until completion of the review action if the petitioner shows—

"(I) a likelihood of success on the merits in such action, and

"(II) that the implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner.

"(ii) A court in a review action under section 16(e) shall not postpone the effective date of a regulation issued under subparagraph (B) if the Administrator shows that failure to implement the regulation before completion of the action would cause a risk of substantial harm to health or the environment.".

SEC. 304. PUBLIC HEARINGS AND SCIENTIFIC REVIEW.

Section 6(d) (7 U.S.C. 136d(d)) is amended—

(1) by striking out the fifth through ninth sentences,

(2) in the tenth sentence—

(A) by striking out "(including the report of the Academy)", and

(B) by striking out "90 days thereafter" and inserting in lieu thereof "18 months after issuance of the notice that gave rise to the hearing",

(3) by inserting before the last sentence the following: "The time period prescribed by the preceding sentence may be extended by the Administrator under extraordinary circumstances for not more than one year.", and

(4) in the heading, by striking out "AND SCIENTIFIC REVIEW".

SEC. 305. ADMINISTRATIVE CHANGES.

(a) AMENDMENT TO SECTION 6.—Section 6 (7 U.S.C. 136d) is amended by inserting the following new subsection after subsection (f) (as added by section 302):

"(g) GENERAL PROVISIONS.—

"(1) VOLUNTARY CANCELLATION.—A registrant at any time may request that any of its pesticide registrations be cancelled or be amended to delete one or more uses. Before acting on any such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter the Administrator may approve such a request.

"(2) PUBLICATION OF NOTICE.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 3A, or a notice issued under the third sentence of subsection (b)(4)(A) shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

"(3) EXISTING STOCKS.—The Administrator may permit the continued use, the continued distribution or sale, or both, of existing stocks of a pesticide whose registration is cancelled under any provision of this Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

"(4) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator. For purposes of this paragraph, the

term 'information' includes factual information and expert opinion regarding risks or benefits.".

(b) CONFORMING AMENDMENTS.—

(1) SECTION 3(c)(6).—Section 3(c)(6) (7 U.S.C. 136a(c)(6)) is amended by striking out the period at the end and inserting in lieu thereof the following: "except as otherwise provided in this paragraph. A request for a hearing under section 6 shall be made within 30 days after the receipt of such notification. The Administrator may issue regulations governing the right to a hearing under section 6 with regard to the denial of any application for the registration of a pesticide containing an ingredient that was cancelled under section 6. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings. Section 6(g)(2) applies with respect to the publication of a notice of a denial of a registration.".

(2) SECTION 6(a)(2).—Section 6(a) (7 U.S.C. 136d(a)) is amended—

(A) by striking out paragraph (2), and

(B) by striking out "(1) PROCEDURE.—", by striking out ": *Provided*" and all that follows in the first sentence and inserting in lieu thereof a period, and inserting the matter in paragraph (1) after the subsection heading so that it is flush with the full left-hand margin of the section.

(3) SECTION 6(e).—Paragraph (1) of section 6(e) (7 U.S.C. 136d(e)) is amended by striking out ": *Provided*" and all that follows in that paragraph and inserting in lieu thereof a period.

SEC. 306. CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.

Section 6 (7 U.S.C. 136d) is amended by inserting the following new subsection after subsection (g) (as added by section 305(a)):

"(h) SUSPENSION AND CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

"(1) NOTICE.—The Administrator shall immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if—

"(A) before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by the registrant of the pesticide to the Administrator in support of such registration were invalid,

"(B) the data referred to in subparagraph (A)—

"(i) have not been replaced as of the effective date of such Act, or

"(ii) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988, and

"(C) such data are material to the registration.

"(2) INVALID DATA.—If, after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator determines that invalid data are submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

"(A) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports, or

"(B) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

"(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue notices of intent to suspend and cancel such registration.

"(4) HEARING.—

"(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on the date of receipt by the registrant of a notice issued under this subsection unless during such period a request for a hearing is made by a person adversely affected.

"(B) A hearing under this paragraph shall be conducted in accordance with the procedures prescribed by subsection (c) or (d), as appropriate.

"(C) In the case of a hearing held with respect to action proposed to be taken under paragraph (1), the only matters for resolution shall be whether—

"(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

"(I) have not been replaced as of the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, or

"(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988, and

"(ii) the data are material to the registration.

"(D) In the case of a hearing held with respect to action proposed to be taken under paragraph (2), the only matters for resolution shall be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

"(E) In the case of a hearing held with respect to action proposed to be taken under paragraph (3), the only matters for resolution shall be whether a registrant willfully submitted material data known to be false.

"(F) A decision after completion of a hearing conducted under this paragraph shall be final.

"(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.".

SEC. 307. TOLERANCES FOR AGRICULTURAL COMMODITIES.

(a) REVOCATIONS AND SUSPENSIONS.—Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) is amended by adding at the end the following:

"(p)(1)(A) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity—

"(i) has been cancelled by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act,

"(ii) has voluntarily been cancelled under such Act, or

"(iii) has voluntarily been withdrawn under such Act,

due in whole or in part to risks to humans, the Administrator, not later than 60 days after the effective date of such cancellation or after receipt of information of such withdrawal, shall revoke any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). In revoking a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used.

"(B) The effective date of a revocation under subparagraph (A) may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

"(i) the use of the cancelled pesticide before the date of its cancellation,

"(ii) the use of existing stocks of such pesticide as authorized under the order cancelling the registration of the pesticide, or

"(iii) unavoidable residual environmental contamination.

"(2) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act due in whole or in part to risks to humans, the Administrator, not later than 60 days after the effective date of such suspension, shall suspend any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). The effective date of such suspension may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

"(A) the use of the suspended pesticide before the date of its suspension,

"(B) the use of existing stocks of such pesticide as authorized under the order suspending the registration of the pesticide, or

"(C) unavoidable residual environmental contamination.

In suspending a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used. The suspension of a tolerance or an exemption from a tolerance for a pesticide chemical shall be effective as long

as the registration of the pesticide to which the tolerance or exemption is applicable is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. If the registration of the pesticide ceases to be suspended and is not cancelled under such Act, the Administrator shall rescind any such suspension of a tolerance or exemption.

"(3) At the time the Administrator makes a determination under section 3A(h)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act regarding an ingredient of a pesticide, any tolerance established under subsection (b) for residues of a pesticide chemical that is or contains such ingredient or any exemption from the need for such a tolerance established under subsection (c) shall be reassessed and such tolerance or exemption shall be established, amended, or revoked as necessary.".

(b) PROCEDURE.—Section 408(m) of such Act (21 U.S.C. 346a(m)) is amended by striking out "The" and inserting in lieu thereof "Except as provided in subsection (p), the".

TITLE IV—RECORDS AND INSPECTIONS

SEC. 401. RECORDS.

(a) SECTION 8.—Section 8 (7 U.S.C. 136f) is amended to read as follows:

"SEC. 8. RECORDS.

"(a) AUTHORITY TO REQUIRE RECORDS.—The Administrator, by regulation, may require any producer or exporter of pesticides, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, or commercial applicator, or any person who distributes or sells any pesticide—

"(1) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act,

"(2) to furnish to the Administrator reports stating the location where the records are maintained, and

"(3) to furnish a copy of any such record to the Administrator on written request.

Except as provided in subsections (c), (d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain, or furnish any record under this subsection with respect to such pesticide.

"(b) LIMITATIONS.—The Administrator may not, under the authority of subsection (a), require any person to maintain records of—

"(1) financial data, sales data, or pricing data,

"(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure, or

"(3) research or test data (other than data relating to registered pesticide, data relating to any pesticide for which an application for registration or for an experimental use permit has

been filed, or data relating to testing at a pesticide testing facility).".

(b) DEFINITION.—Section 2 (7 U.S.C. 136) (as amended by section 105(c)) is amended by adding at the end the following:

"(hh) PESTICIDE TESTING FACILITY.—The term 'pesticide testing facility' means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing it). The term does not include any person solely on account of such person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit under section 5.".

(c) CONFORMING AMENDMENTS.—The second sentence of section 26(c) (7 U.S.C. 136w-1(c)) is amended—

(1) by striking out "8(b) of this Act" and inserting in lieu thereof "9",

(2) by striking out "9(a) of this Act" and inserting in lieu thereof "9", and

(3) by striking out "Not withstanding the provisions of section 2(e)(1) of this Act" and inserting in lieu thereof "Notwithstanding section 2(kk)".

SEC. 402. INSPECTIONS.

(a) SECTION 9(a).—Section 9(a) (7 U.S.C. 136g(a)) is amended to read as follows:

"(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—Officers or employees of the United States or of any State, duly designated by the Administrator, are authorized at reasonable times, as provided by this section—

"(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device,

"(2) to enter any place where there are located any records required under this Act or any place reported under section 8(a) as a location where such records are maintained, to inspect and obtain copies of such records,

"(3) to enter any pesticide testing facility, to inspect the facility and the testing being conducted at the facility and to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility, and

"(4) to enter any place where such officer or employee has reason to believe that the Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, to inspect such place to obtain evidence of such violation.".

(b) SECTION 9(b).—Section 9(b) (7 U.S.C. 136g(b)) is amended to read as follows:

"(b) WARRANTS.—Officers or employees of the United States or of any State, duly designated by the Administrator, are empowered to obtain and execute warrants authorizing—

"(1) entry for the purposes of this section,

"(2) inspection and copying of all records required under this Act, and

"(3) seizure of any pesticide or device that is in violation of this Act.".

(c) PROCEDURE AND COORDINATION.—Section 9 (7 U.S.C. 136g) is further amended by adding at the end the following:

"(d) PROCEDURE.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the entry or inspection and whether a violation of this Act is suspected. Each entry or inspection shall be commenced and completed with reasonable promptness. If the person conducting the entry or inspection obtains any samples of pesticides or devices, before leaving the premises such person shall give to the person in charge of the premises a receipt describing the samples and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished on request to the person in charge of the premises.

"(e) COORDINATION.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication of inspections.".

TITLE V—EXPORTS

SEC. 501. DEFINITION OF MISBRANDED.

Section 2(q)(1) (7 U.S.C. 136(q)(1)) is amended—

(1) by striking out "or" at the end of subparagraph (G),

(2) by striking out the period at the end of subparagraph (H) and inserting after the closing quotation marks "; or", and

(3) by adding at the end thereof the following new subparagraph:

"(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label is not written in an appropriate language as required by section 17(a)(4)(A) or does not contain the same health, safety, and hazard precautions as the pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country.".

SEC. 502. DEFINITION OF IMPORTING COUNTRY.

Section 2 (7 U.S.C. 136) (as amended by section 401(b) of this Act) is amended by adding at the end thereof the following new subsection:

"(ii) IMPORTING COUNTRY.—The term 'importing country' means the first country to which a pesticide, device, or active ingredient,

subject to the notification requirements of section 17(a), is exported from the United States.".

SEC. 503. PESTICIDES AND DEVICES INTENDED FOR EXPORT.

(a) IN GENERAL.—Subsection (a) of section 17 (7 U.S.C. 136o(a)) is amended to read as follows:

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

"(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device, or active ingredient used in producing a pesticide, intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to section 2(p), subparagraphs (A), (C), (D), (E), (G), (H), and (I) of section 2(q)(1), subparagraphs (A), (B), (C)(i), (C)(iii), and (D) of section 2(q)(2), sections 7 and 8, and paragraphs (2), (3), and (4) of this subsection.

"(2) RESTRICTED USE OR UNREGISTERED PESTICIDES.—

"(A) This paragraph applies to a pesticide, device, or active ingredient—

"(i) for which a restricted use classification has become effective under section 3,

"(ii) for which a cancellation or suspension has become effective under section 6,

"(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal is associated with concern over potential adverse public health or environmental effects, or

"(iv) that is not registered under section 3 for any use.

"(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless, at least 30 days before the first shipment each year of such pesticides, devices, or active ingredients to such country, such person has—

"(i) notified, under paragraph (3), the person importing the pesticide, device, or active ingredient and the appropriate government regulatory office in the importing country,

"(ii) received written evidence that the notification was delivered to the appropriate government regulatory office, and

"(iii) submitted a copy of the notification (in English) and evidence of delivery to the Administrator.

"(C) Documents referred to in subparagraph (B) shall be made available to the public, on request.

"(3) NOTIFICATION SPECIFICATIONS.—The notification required under paragraph (2) shall be made in an appropriate language and shall contain the following information—

"(A) the name of the pesticide and the common and chemical names of each active ingredient,

"(B) the name and address of the person exporting the pesticide, device, or active ingredient,

"(C) the name and address of the person importing the pesticide, device, or active ingredient,

"(D) the name and address of the appropriate government regulatory office in the importing country,

"(E) a statement of the reasons why the registration of the pesticide was cancelled, suspended, voluntarily withdrawn, or the pesticide is not registered in the United States or is classified for restricted use, and the list of restrictions, and

"(F) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

"(4) LABELS.—

"(A) The label of a pesticide intended for export from the United States shall be written in an appropriate language.

"(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.

"(5) RECORDS.—The Administrator, by regulation, may require any person subject to this subsection to prepare, maintain, and submit such records as may be necessary to carry out this subsection.".

(b) EFFECTIVE DATES AND IMPLEMENTATION.—

(1) Section 17(a)(2) and (3) of the Federal Insecticide, Rodenticide, and Fungicide Act (as amended by subsection (a) of this section) shall become effective 90 days after the date of enactment of this Act.

(2) Not later than 30 days after the date of enactment of this Act, the Administrator of the Environmental Protection Agency shall publish in the Federal Register a list of the names, addresses, and international telecommunications codes of appropriate regulatory offices required to receive notices under section 17(a)(2)(B) of the Federal Insecticide, Rodenticide, and Fungicide Act, as amended by subsection (a).

(3) Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Administrator shall revise the list required under paragraph (2).

(4) Not later than 90 days after the date of enactment of this Act, the Administrator shall publish in the Federal Register preliminary guidelines regarding—

(A) the form of the notification required under section 17(a) of the Federal Insecticide, Rodenticide, and Fungicide Act, as amended by subsection (a),

(B) translation of the notification and labels required under such section 17(a) into the appropriate language,

(C) preparation and retention of records under such section 17(a), and

(D) procedures for public access to documents submitted by exporters under such section.

SEC. 504. CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.

Subsection (b) of section 17 (7 U.S.C. 136o(b)) is amended to read as follows:

"(b) NOTICES OF REGULATORY ACTION FURNISHED TO FOREIGN GOVERNMENTS.—

"(1) ISSUANCE.—Whenever—

"(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective, or

"(B) a pesticide is classified for restricted use,

the Administrator shall promptly transmit through the Secretary of State a notice, at such time and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies.

"(2) CONTENTS.—A notice under paragraph (1) shall include—

"(A) the reasons for the regulatory action taken,

"(B) for canceled or suspended registrations, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide, and

"(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.".

SEC. 505. COOPERATION IN INTERNATIONAL EFFORTS.

Subsection (d) of section 17 (7 U.S.C. 136o(d)) is amended to read as follows:

"(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

"(1) in cooperation with the Secretary of State, other appropriate Federal agencies, and nongovernmental and international organizations, actively participate in international efforts to develop improved pesticide research and regulatory programs,

"(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs,

"(3) within 1 year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, and every 3 years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to ascertain what procedures are in place in each country—

"(A) regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides, and

"(B) to control residues on foods to meet tolerances established under United States law, and

"(4) report to Congress annually on the activities conducted under this subsection and the results thereof.".

TITLE VI—CERTIFICATION AND TRAINING

SEC. 601. CERTIFICATION, TRAINING, AND RECORDKEEPING FOR PESTICIDE APPLICATORS.

(a) DEFINITIONS.—

(1) Section 2(e) (7 U.S.C. 136(e)) is amended to read as follows:

"(e) APPLICATOR.—

"(1) COMMERCIAL APPLICATOR.—

"(A) Except as provided in subparagraph (B), the term 'commercial applicator' means a person (whether or not the person is a private applicator with respect to some uses) who—

"(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use,

"(ii) uses or supervises the use of any pesticide for hire as the principal part of the person's business or work, or

"(iii) as an employee of a person described in clause (ii), uses or supervises the use of any pesticide.

"(B) The term does not include a person who uses or supervises the use of a pesticide as described in paragraph (2).

"(2) PRIVATE APPLICATOR.—The term 'private applicator' means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity—

"(A) on property owned or rented by such person or such person's employer, or

"(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

"(3) CERTIFIED APPLICATOR.—The term 'certified applicator' means a commercial or private applicator who is certified under section 4.

"(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is used.".

(2) Section 2 (as amended by section 502) is amended by adding at the end the following:

"(jj) PESTICIDE DEALER.—

"(1) Except as provided in paragraph (2), the term 'pesticide dealer' means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or designated under section 8(d)(2).

"(2) Such term does not include a person who only distributes or sells pesticides that are classified for general use and that are not designated under section 8(d)(2).".

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(b) SECTION 4.—

(1) Section 4 (7 U.S.C. 136b) is amended by adding at the end the following:

"(d) PROVISIONS REGARDING COMMERCIAL APPLICATORS.—

"(1) It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is—

"(A) a certified commercial applicator, or

"(B) a registered commercial applicator under the direct supervision of a certified applicator who is a certified commercial applicator.

"(2) To be considered to be a certified commercial applicator, a person, at a minimum, shall—

"(A) have met the standards prescribed under subsection (a) and have received training—

"(i) prescribed by the State agency, including training in the material referred to in subsection (g),

"(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

"(iii) that satisfies the minimum standards for training programs prescribed under subsection (h),

"(B) have had field, institutional, or industrial experience in pesticide use and application,

"(C) have passed an examination prescribed by such State agency, and

"(D) possess a valid commercial applicator certification issued by such State agency.

"(3) To be considered to be a registered commercial applicator, a person, at a minimum, shall—

"(A) have received training—

"(i) prescribed by the State agency, including training in the material referred to in subsection (g), and

"(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

"(B) possess a valid registration issued by such State agency.

A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

"(e) PROVISIONS REGARDING PRIVATE APPLICATORS.—

"(1) A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if it is applied by a person who is either—

"(A) a certified private applicator, or

"(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

"(2) To be considered to be a certified private applicator, a person, at a minimum, shall—

"(A) have met the standards prescribed under subsection (a) and have received training—

"(i) prescribed by the State agency, including training in the material described in subsection (g),

"(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

"(iii) that satisfies the minimum standards for training prescribed under subsection (h), and

"(B) possess a valid private applicator certification issued by such State agency.

"(3) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction—

"(A) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling, and

"(B) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A) has been received.

"(f) RECERTIFICATION AND REREGISTRATION.—Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the State agency of such State. Such period may not be more than 5 years. The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14. To be recertified, an applicator, at a minimum, shall meet the requirements of paragraphs (2)(A), (2)(B), and (2)(D) of subsection (d) or the requirements of paragraphs (1) and (2) of subsection (e). To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

"(g) TRAINING MATERIAL.—The Administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling. Within 12 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator, in consultation with the Secre-

tary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

"(h) MINIMUM STANDARDS FOR TRAINERS AND TRAINING PROGRAMS.—

"(1)(A) The Administrator shall establish within one year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986—

"(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d), and

"(ii) minimum standards for the training programs referred to in subsection (d).

"(B) Training programs prescribed by any State under subsection (d) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring its training program into compliance with such standards. If on expiration of such 90-day period, the State's training program does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

"(2)(A) The Administrator shall establish within 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986—

"(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e), and

"(ii) minimum standards for the training programs referred to in subsection (e).

"(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring its training program into compliance with such standards. If on expiration of such 90-day period the State's training program does not meet such standards, the Administrator shall prescribe the training programs referred to in subsection (e) for use in such State.

"(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.—A State agency may approve any privately administered training program that it determines meets—

"(1) the requirements established under this section, or

"(2) requirements established by the State agency,

whichever are more stringent.

"(j) ENFORCEMENT OFFICER TRAINING.—Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, as a minimum, includes training covering materials specified in subsection (g) for the com-

mercial application categories for which they are assigned enforcement responsibility.

"(k) SEPARATE STANDARDS.—In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

"(l) STATE AGENCY DEFINED.—For purposes of this section, the term 'State agency' means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforcement responsibility or that does not have an agency designated under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.".

(2)(A)(i) Except as provided in clauses (ii) and (iii), subsection (d) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by paragraph (1)) shall take effect in a State on the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (d) are to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(ii) If an applicator in a State is certified as a commercial applicator under subsection (a) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act before the effective date prescribed by clause (i) and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d) of such section, such applicator shall be recertified—

(I) within 2 years after the date the training programs of such State under subsection (d) comply with such minimum standards of the Administrator, or

(II) within such earlier time as the State may prescribe.

(iii) The requirements of subsection (d) of section 4 for registered commercial applicators shall take effect 1 year after the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (d) are to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(B)(i) Except as provided in clauses (ii) and (iii), subsection (e) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by paragraph (1)) shall take effect in a State on the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (e) are to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(ii) If an applicator in a State is certified as a private applicator under subsection (a) of section 4 before the effective date prescribed by clause (i) and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d) of such section, such applicator shall be recertified—

(I) within 2 years after the date the training programs of such State under subsection (e) comply with such minimum standards of the Administrator, or

(II) within such earlier time as the State may prescribe.

(iii) The requirements of subsection (e) of section 4 for supervised private applicators shall take effect 1 year after the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (e) are to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under such subsection.

(C) The requirements of subsection (j) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by paragraph (1)) shall take effect 1 year after the Administrator issues the training materials specified in subsection (g) of such section.

(c) SECTION 8.—

(1) Section 8 (7 U.S.C. 136f) (as amended by section 401) is amended by adding at the end the following:

"(c) RECORDS OF APPLICATORS.—

"(1) COMMERCIAL APPLICATORS.—The Administrator shall require each commercial applicator to maintain records of each pesticide application, including the identity and amount of pesticide applied and the date and location of such application, for a period of 2 years after each such application.

"(2) PRIVATE APPLICATORS.—No regulations issued by the Administrator to carry out this Act may require any private applicator to maintain any records or file any reports or other documents.

"(d) RECORDS OF PESTICIDE DEALERS.—The Administrator, by regulation, shall require each pesticide dealer to maintain a record of each sale or distribution of—

"(1) a pesticide classified for restricted use, and

"(2) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer shall maintain the records required under this subsection for 3 years after the date of the distribution or sale.

"(e) ACCESS.—

"(1)(A) Any pesticide dealer or commercial applicator shall afford to any employee or former employee of such dealer or applicator access to records required to be kept under subsections (c) and (d) that directly relate to the employee's employment duties.

"(B) Any pesticide dealer or commercial applicator shall afford to any customer of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide

application made by such an applicator at the request of the customer or under a contract with a customer.

"(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

"(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph, except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours after the request is made.

"(2) A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 on request by such State agency to the commercial applicator or dealer required to maintain such records.

"(f) INFORMATION FOR EMPLOYEES.—An employer who uses or supervises the use of a pesticide shall know or have access to the brand name and common or chemical name of the pesticide and to the safety, first aid, and antidote information listed on the labeling of the pesticide and shall be responsible for promptly making such information available, on request, to any employee exposed to the pesticide and to treating medical personnel.".

(2) Section 11 (7 U.S.C. 136i) is repealed.

(d) SECTION 12.—Section 12(a)(2) (7 U.S.C. 136j(a)(2)) is amended by striking out "or" at the end of subparagraph (O), by striking out the period at the end of subparagraph (P) and inserting in lieu thereof a semicolon, and by adding after subparagraph (P) the following:

"(Q) to obtain and use records acquired under section 8(e) in furtherance of a commercial purpose;".

TITLE VII—DATA COMPENSATION

SEC. 701. DEFENSIVE DATA.

(a) AMENDMENTS.—

(1) Section 3(c)(2)(B)(ii) (7 U.S.C. 136a(c)(2)(B)(ii)) is amended to read as follows:

"(ii)(I) Each registrant of a pesticide for which a notice is issued under clause (i) shall provide evidence within 90 days after receipt of such notification that it is taking appropriate steps to secure the additional data that are required under such notice.

"(II) Each registrant of a pesticide that contains an active ingredient that is only used for application in the production of food, feed, or fiber shall, by the ninetieth day after notification, agree to develop jointly the additional data concerning that active ingredient

that are required under such notice or to share in the cost of developing such data and advise the Administrator of their intent. Any such registrant who agrees to develop jointly, or to share in the cost of producing, the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

"(III) In the case of any other pesticide, two or more registrants of such pesticides may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within 90 days after notification. Any such registrant who agrees to develop jointly, or to share in the cost of producing, the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

"(IV) If a pesticide contains active ingredients that are used for application in the production of food, feed, or fiber and for other purposes, the registrants of the pesticide who are subject to a requirement to submit additional data shall be subject to subclause (II) or (III), whichever the majority of the registrants of the pesticide shall agree to.".

(2) The first sentence of section 3(c)(2)(B)(iv) (7 U.S.C. 136a(c)(2)(B)(iv)) is amended by inserting after "under this subparagraph" the following: "or if the Administrator determines that a registrant has failed to take the action required by clause (ii)(II)".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect with respect to notices issued under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

SEC. 702. DATA COMPENSATION AND ARBITRATION.

Section 3(c)(1)(D)(ii) (7 U.S.C. 136a(c)(1)(D)(ii)) is amended by inserting "(I)" after "(ii)" adding at the end the following:

"(II) If the term of a patent for a pesticide registered under this section is extended after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 under an Act of Congress that amends title 35, United States Code, to authorize an extension of the term of a patent for a pesticide that had not expired before the date of enactment of such Act of Congress irrespective of the date the pesticide completed a regulatory review period as defined in such title, the amount of compensation to be paid under arbitration under subclause (I) for the use of data submitted to the Administrator for such pesticide shall be a fair share of the cost of producing the data plus a value premium not to exceed that share, as determined in the arbitration process.

"(III) In the case of a pesticide the term of the patent for which has expired, the terms and amount of

compensation, for data that was submitted for such pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data may be fixed before the submission of such application by arbitration under subclause (I) initiated by such person. The arbitration shall be binding on the original data submitter and shall be binding on such person after the date such persons's application is submitted. Each party to the first arbitration under this subclause to determine the terms and amount of compensation for the use of particular data shall share equally in the payment of the fees and expenses of the arbitrators and shall each pay its own attorney's fees. In all subsequent arbitrations under this subclause to determine the terms and amount of compensation for the use of such data, the party to such subsequent arbitration who seeks to cite the data of the original data submitter shall pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter. The provisons of subclause (I) apply to arbitrations under this clause, except as otherwise provided in this subclause.".

TITLE VIII—GENERAL

Subtitle A—Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act

SEC. 801. STATE REGISTRATIONS.

Section 24(c) (7 U.S.C. 136v(c)) is amended—

(1) by striking out the period at the end of paragraph (1) and inserting in lieu thereof a comma and the following: "and such registration shall expire and be of no further effect, without further action by the Administrator—

"(A) at the end of the period, if any, provided as the duration of the registration by the State that approved it, or

"(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.", and

(2) by adding at the end of paragraph (2) the following: "The Administrator shall establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use.".

SEC. 802. DEFINITIONS.

(a) AMENDMENTS.—

(1) SECTION 2(bb).—Section 2(bb) (7 U.S.C. 136(bb)) is amended by adding at the end the following: "For purposes of this subsection, the term 'man' includes unborn human beings from the moment of conception.".

(2) SECTION 2(ee).—Section 2(ee) (7 U.S.C. 136(ee)) is amended—

(A) by inserting before the comma at the end of clause (1) "unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency", and

(B) in clause (3), by inserting after "labeling" the following: "unless the labeling specifically states that the product may be applied only by the methods specified on the labeling".

(3) NEW DEFINITION.—Section 2 (as amended by section 601(a)(2)) is amended by adding at the end the following:

"(kk) TO DISTRIBUTE OR SELL.—The term 'to distribute or sell' means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.".

(b) CONFORMING AMENDMENTS.—

(1) Section 3(a) (7 U.S.C. 136a(a)) is amended to read as follows:

"(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act.".

(2) Section 12(a) (7 U.S.C. 136j(a)) is amended—

(A) in paragraph (1) by striking out "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—" and inserting in lieu thereof "distribute or sell to any person—", and

(B) in paragraph (2)(F) by striking out "to make" and inserting in lieu thereof "to distribute or sell, or to make".

SEC. 803. INFORMATION REQUESTED.

Section 7 (7 U.S.C. 136e) (as amended by section 201) is amended by adding at the end the following:

"(f) INFORMATION REQUESTED.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall catalogue and retrieve data in such manner as to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data.".

SEC. 804. COOPERATIVE AGREEMENTS.

Section 23(a) (7 U.S.C. 136u(a)) is amended to read as follows:

"(a) COOPERATIVE AGREEMENTS.—The Administrator may enter into cooperative agreements with States and Indian Tribes for the following:

"(1) To delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian Tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants.

"(2) To provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as agreed under such cooperative agreements, of conducting training programs for certification of applicators. Funds shall be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator.

"(3) To provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under such cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State plan of each State approved under section 4(a)(2). Funds shall be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under this subsection.".

SEC. 805. SCIENTIFIC ADVISORY PANEL.

Section 25(d) (7 U.S.C. 136w(d)) is amended—

(1) by striking out "consist of 7 members" and inserting in lieu thereof "be permanent and consist of 9 members", and

(2) by striking out the sentence beginning "The advisory panel established".

SEC. 806. AUTHORITY FOR EPA ACTION.

The second sentence of section 27(a) (7 U.S.C. 136w-2(a)) is amended to read as follows: "If a State—

"(1) does not promptly initiate appropriate investigative action after receiving such referral, or

"(2) does not initiate appropriate enforcement action within 90 days after receipt of such referral,

the Administrator may act on such complaint or information in accordance with this Act.".

SEC. 807. EXPIRATION OF STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

Section 26 (7 U.S.C. 136w-1) is amended by adding at the end the following:

"(d) EXPIRATION.—Notwithstanding subsections (a) and (b), the primary enforcement responsibility of a State under this section for pesticide use violations shall expire on January 1, 1989, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14.".

SEC. 808. UNLAWFUL ACTS.

(a) SECTION 12(a).—Section 12(a) (7 U.S.C. 136j(a)) (as amended by section 601(d)) is amended—

(1) by amending paragraph (1)(A) to read as follows:

"(A) any pesticide that is not registered under section 3 or whose registration has been cancelled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;",

(2) by amending paragraph (2)(B) to read as follows:

"(B) to refuse to (i) prepare, maintain, or submit any records required by or under this Act, (ii) submit any reports required by or under this Act, or (iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;",

(3) by amending paragraph (2)(J) to read as follows:

"(J) to violate any suspension order issued under section 3(c)(2)(B), 3A, or 6;",

(4) by amending paragraph (2)(K) to read as follows:

"(K) to violate any cancellation order issued under this Act;",

(5) in paragraph (2)(M), by striking out "section 8" and inserting in lieu thereof "this Act", and

(6) by adding at the end of paragraph (2) the following:

"(R) to willfully falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

"(S) to willfully submit to the Administrator data known to be false in support of a registration; or

"(T) to violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25(f) of this Act.".

(b) ACTS OF OFFICERS, AGENTS, ETC.—

(1) Section 12 (7 U.S.C. 136j) is amended by adding at the end the following:

"(c) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall be deemed to be the act, omission, or failure of such person as well as that of the person employed.".

(2) Paragraph (4) of section 14(b) (7 U.S.C. 136l(b)) is repealed.

SEC. 809. PENALTIES AND SUBPOENAS.

(a) SECTION 14(a).—Section 14(a) (7 U.S.C. 1361(a)) is amended—

(1) by amending paragraph (1) to read as follows:

"(1) IN GENERAL.—

"(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If a registrant, applicant for a registration, producer, or pesticide testing facility violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $50,000 for such subsequent violation.

"(B) Any—

"(i) commercial applicator of restricted use pesticides, or

"(ii) any other person not described in subparagraph (A) who distributes or sells pesticides or devices,

that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $20,000 for such subsequent violation.",

(2) by amending paragraph (2) to read as follows:

"(2) PRIVATE APPLICATOR.—Any private applicator who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, and any other person not included in paragraph (1) that violates any provision of this Act, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $2,000 for such subsequent violation. The Administrator may waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment.",

(3) by adding at the end of paragraph (3) the following: "If the person neither resides nor has its principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties.", and

(4) in the first sentence of paragraph (4), by inserting "the economic benefit (if any) resulting from the violation," after "to continue in business,".

(b) SECTION 14(b).—

(1) Section 14(b)(1) (7 U.S.C. 1361(b)(1)) is amended to read as follows:

"(1) IN GENERAL.—

"(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that knowingly violates any provision of this Act shall be fined not more than $50,000 or imprisoned for not more than one year, or both.

"(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, that knowingly violates any provision of this Act shall be fined not more than $25,000 or imprisoned for not more than one year, or both.".

(2) Section 14(b)(2) (7 U.S.C. 1361(b)(2)) is amended (A) by striking out "$1,000" and inserting in lieu thereof "$2,000", and (B) by striking out "30" and inserting in lieu thereof "60".

(c) SUBPOENAS.—Section 14(a) (7 U.S.C. 1361(a)) is amended by adding at the end the following:

"(6) SUBPOENAS.—The Administrator, in connection with administrative proceedings under this subsection, may issue subpoenas compelling the attendance and testimony of witnesses

and subpoenas duces tecum and may request the Attorney General to bring an action to enforce any subpoena issued under this paragraph. The district courts of the United States shall have jurisdiction to enforce such subpoenas and impose sanctions.".

SEC. 810. CONGRESSIONAL REVIEW.

Section 25(a)(4) (7 U.S.C. 136w(a)(4)) is amended to read as follows:

"(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.".

SEC. 811. REVIEW OF REGULATIONS.

Section 16 (7 U.S.C. 136n) is amended by adding at the end thereof the following:

"(e) REVIEW OF REGULATIONS.—

"(1)(A) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the regulation by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any petition under this paragraph for review of a regulation shall be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register.

"(B) Any refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a refusal to modify or rescind a regulation shall be filed within 120 days after such refusal.

"(C) The scope of review under subparagraph (A) or (B) shall be as specified in section 706 of title 5, United States Code. The commencement of a proceeding under subparagraph (A) or (B), unless specifically ordered by the court to the contrary, shall not operate as a stay of the regulation.

"(2) A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall not be subject to judicial review—

"(A) in any suspension, cancellation, or denial proceeding under this Act or in any appeal therefrom, or

"(B) in any proceeding under section 13 or 14(a), or subsection (c), or in any appeal therefrom except on request of a person who, as an agricultural producer, is adversely affected by such action.

"(3) If a person who is a party to a proceeding described in subparagraph (A) or (B) of paragraph (2) that is based on a regulation issued under this Act petitions the Administrator to modify or rescind such regulation, the application of such regulation in the proceeding shall be stayed until the Administrator issues a final decision on the petition.

"(4) As used in this subsection, the term 'agricultural producer' means a nongovernmental producer of agricultural commodities who (A) uses or supervises the use of any pesticide for the production of such commodities on property owned or rented by the producer or the producer's employer, or (B) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on such producer's land.".

SEC. 812. DELEGATION AND COOPERATION.

Section 22 (7 U.S.C. 136t) is amended by adding at the end the following:

"(c) EFFECT ON CERTAIN OTHER LAWS.—The Administrator, in exercising any authority under this Act, shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that such exercise of authority by the Administrator under this Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1). To ensure the safety and health of workers, the Administrator and the Secretary of Labor shall seek to reach such agreements and to coordinate the exercise of their statutory authority.".

SEC. 813. INDEMNITY REPORT BY EPA.

Section 15 (7 U.S.C. 136m) is amended by adding at the end the following:

"(c) REPORT.—If the Administrator takes an action that under subsection (a) requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate—

"(1) the action taken that requires the payment of indemnification,

"(2) the reasons for taking such action,

"(3) the estimated cost of the payment,

"(4) the effect such payment would have on the budget of the Administrator to implement this Act without a specific additional appropriation for the payment, and

"(5) a request for the appropriation of funds for such payment.".

SEC. 814. GROUNDWATER AUTHORITY.

The Act (as amended by section 202) is amended by adding after section 31 the following:

"SEC. 32. GROUNDWATER AUTHORITY.

"(a) IN GENERAL.—The Administrator, as appropriate and necessary, shall use the authorities under this Act to provide for the protection of drinking water and groundwater against contamination by pesticides.

"(b) USE OF OTHER AUTHORITIES.—In carrying out subsection (a), the Administrator shall use maximum contaminant levels established under title XIV of the Public Health Service Act, whenever available, as groundwater residue guidance levels.

"(c) CONSULTATION WITH STATES.—In carrying out subsection (a), the Administrator shall consult with, and take into account the views of, the States on—

"(1) the distinction between drinking water, shallow groundwater that is not a potential source of drinking water, and groundwater that is a potential source of drinking water,

"(2) degradation of pesticides in groundwater, and

"(3) appropriate means for responding to and preventing pesticide contamination of drinking water and groundwater.

"(d) CONSULTATION WITH SECRETARY OF AGRICULTURE.—In carrying out subsections (a) and (c), the Administrator shall consult with the Secretary of Agriculture.".

SEC. 815. WORKER HEALTH AND SAFETY.

Section 25 (7 U.S.C. 136w) is amended by adding at the end the following:

"(f) WORKER HEALTH AND SAFETY.—

"(1)(A) The Administrator, as soon as practicable, shall promulgate regulations that require the protection, as appropriate and necessary, of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas.

"(B) The Administrator shall promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement that may be established by the Administrator under this subparagraph shall not apply to any person who is required to receive the training described in subsection (d) or (e) of section 4.

"(C) For purposes of subparagraphs (A) and (B), the term 'employees' does not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

"(2)(A) The Administrator shall promulgate regulations under paragraph (1) for employees not described in subparagraph (B) not later than 3 years after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

"(B) The Administrator shall provide a period of at least 6 months for comments on proposed regulations issued under paragraph (1) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas.

Such regulations shall be promulgated not later than 2 years after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

"(3) Not later than 6 months after the date of the publication of the notice of proposed rulemaking issued for the regulations for employees described in paragraph (2)(B) to be promulgated under paragraph (1), the Secretary of Agriculture shall submit to the Administrator a report on the impact, cost, and effectiveness of such regulations on the agricultural community. The Secretary shall submit a copy of such report to Congress.

"(4) Simultaneously with the promulgation of regulations under paragraph (1), the Administrator shall transmit a copy of such regulations to the Secretary of the Senate and the Clerk of the House of Representatives. Such regulations may not become effective until the expiration of 120 days after the date such regulations are so transmitted.".

SEC. 816. AUTHORIZATION FOR APPROPRIATIONS.

Effective October 1, 1986, section 33 (7 U.S.C. 136y) (as redesignated by section 202(b)) is amended to read as follows:

"SEC. 33. AUTHORIZATION FOR APPROPRIATIONS.

"There is authorized to be appropriated to carry out this Act (other than sections 23(a) and 31) $78,363,500 for fiscal year 1987, of which not more than $13,735,500 shall be available for research under this Act, $87,414,200 for fiscal year 1988, of which not more than $14,343,600 shall be available for research under this Act, $91,673,400 for fiscal year 1989, of which not more than $14,978,200 shall be available for research under this Act, $98,305,800 for fiscal year 1990, of which not more than $15,625,900 shall be available for research under this Act, and $106,808,700 for fiscal year 1991, of which not more than $16,300,100 shall be available for research under this Act.".

Subtitle B—Other Provisions

SEC. 821. LIABILITY.

(a) PESTICIDE USE.—An agricultural producer shall not be liable in any action brought after the effective date of this Act under any Federal statute for damages caused by pesticide use unless the producer has acted negligently, recklessly, or intentionally. Proof that the agricultural producer used the pesticide in a manner consistent with label instructions shall create a rebuttable presumption that the agricultural producer did not act negligently.

(b) FIFRA PENALTIES.—An agricultural producer shall not be held liable in an action brought under section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act for civil penalties for a violation of section 12(a)(2)(G) of such Act unless the producer used the pesticide in a manner inconsistent with its labeling. Proof that the pesticide was used in a manner consistent with its label instructions shall create a rebuttable presumption that the agricultural producer did not violate such subsection.

(c) DEFINITION.—As used in this section, the term "agricultural producer" means a nongovernmental producer of agricultural com-

modities who (1) uses or supervises the use of any pesticide for the production of such commodities on property owned or rented by the producer or the producer's employer, or (2) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on such producer's land.

SEC. 822. EVALUATION BY THE COMPTROLLER GENERAL.

(a) EVALUATION.—The Comptroller General of the United States shall conduct an evaluation of the programs and activities authorized by the amendments to the Federal Insecticide, Fungicide, and Rodenticide Act made by this Act and shall make a final report of such evaluation to Congress no later than December 31, 1988. The Comptroller General shall include in such evaluation the effect that the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, is having on the cost and availability of pesticides to farmers as well as other producers of food and fiber. Such evaluation shall include an analysis of the reregistration program under such Act and any program conducted by the Administrator of the Environmental Protection Agency under such Act relating to groundwater.

(b) RECORDS.—For the purpose of conducting program evaluations required under subsection (a), the Comptroller General, or the duly authorized representatives of the Comptroller General, shall have access to and the right to examine all documents, papers, records, data, pesticide study documentation, or other recorded information within the possession or control of the Administrator of the Environmental Protection Agency or within the possession or control of pesticide registrants subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act. The Comptroller General and the representatives of the Comptroller General shall be subject to the same restrictions regarding the disclosure of trade secret information as are the employees of the Environmental Protection Agency.

SEC. 823. IR4 PROGRAM.

Section 2(c) of the Act of August 4, 1965 (7 U.S.C. 450i(c)), is amended by inserting before the first sentence after paragraph (2) the following: "The Secretary in making grants under paragraph (2)(B) shall provide support for the interregional project number 4 program (commonly referred to as the 'IR4 program').".

SEC. 824. PESTICIDE RISK RATING.

(a) STUDY.—Subject to subsection (b), the Administrator of the Environmental Protection Agency shall contract with the Board of Agriculture of the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricultural commodities. Such risk rating shall take into consideration methods of application, chronic and acute toxicity, and anticipated losses to and persistence in the environment. In conducting the study, the National Academy of Sciences shall seek information and advice from recognized public and private sector scientists and provide opportunity for public comment on the preliminary findings relating to the development of a risk rating. The National

Academy of Sciences shall report the findings of such study to the Administrator and to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate within 18 months after the date of the enactment of this Act.

(b) LIMITATION.—The study required by subsection (a) shall be conducted at such cost as the Administrator, in consultation with the National Academy of Sciences, may establish.

(c) CONTRACT AUTHORITY.—The authority of the Administrator to enter into contracts under this section shall be effective only to such extent or in such amounts as are provided in advance in appropriation Acts.

SEC. 825. STUDY OF NONAGRICULTURAL PESTICIDES.

The Administrator of the Environmental Protection Agency shall study and report to Congress within one year after the date of the enactment of this Act on the pesticide volume, use sites, and target insects for nonagricultural pesticides.

SEC. 826. DIOXIN STUDY.

The Administrator of the Environmental Protection Agency shall collect and analyze samples of human breast milk for residues of isomers of chlorinated dioxins and dibenzofurans. Not later than 2 years after the date of the enactment of this Act, the Administrator shall report to Congress the findings from the analysis of such samples.

SEC. 827. PESTICIDE DRIFT.

The Administrator of the Environmental Protection Agency, within 2 years after the date of enactment of this Act, shall report to the Committee on Agriculture of the House of Representatives and to the Committee on Agriculture, Nutrition, and Forestry of the Senate on the incidence and potential adverse effects on human health and the environment of the drift of pesticides from the site of application at the time of application.

SEC. 828. SURVEY OF NATURALLY OCCURRING AGENTS THAT ACT AS PESTICIDES.

The Administrator of the Environmental Protection Agency shall conduct a survey to determine what research has been, or is being, conducted to establish the extent to which agents that act as pesticides are manufactured by plants and thereby exist naturally in fruits, vegetables, grains, legumes, and oilseeds commonly consumed by persons in the United States. The Administrator shall provide a report on the findings of the survey to the Committee on Agriculture of the House of Representatives and to the Committee on Agriculture, Nutrition, and Forestry of the Senate not later than December 31, 1987, and shall release such findings to the public. The report shall include information on the extent to which such naturally occurring agents have been identified, the nature of such agents, and the extent to which such agents have been shown to be toxic, carcinogenic, or mutagenic.

TITLE IX—CLARIFYING AND TECHNICAL AMENDMENTS

SEC. 901. CLARIFYING AMENDMENTS.

(a) SECTION 3.—

(1) Section 3(a) (7 U.S.C. 136a(a)) (as amended by section 802(b)) is amended by adding at the end the following: "To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.".

(2) Section 3(d) (7 U.S.C. 136a(d)) is amended—

(A) in paragraph (1)(A), by striking out "on the initial classification", and

(B) in paragraph (1)(C), by striking out the colon preceding clause (i) and inserting in lieu thereof a period, by striking out clause (i), by striking out "(ii)", and by running in the material after "restricted use." so that the margin is the same as the margin of paragraph (1)(C).

(3) Section 3(c)(7)(A) (7 U.S.C. 136a(c)(7)(A)) is amended—

(A) by striking out "submit" each place it occurs and inserting in lieu thereof "submit or cite",

(B) by striking out "submission" and inserting in lieu thereof "submission or citation", and

(C) by striking out "submitted" and inserting in lieu thereof "submitted or cited".

(b) SECTION 4.—The last sentence of section 4(a)(1) (7 U.S.C. 136b(a)(1)) is amended by inserting "by regulation" after "may".

(c) SECTION 7.—Section 7(c) (7 U.S.C. 136e(c)) is amended—

(1) by striking out "shall inform the Administrator" and inserting in lieu thereof "shall, in accordance with regulations promulgated by the Administrator, submit to the Administrator a report",

(2) by striking out "of the" and inserting in lieu thereof "describing", and

(3) by striking out "information" and inserting in lieu thereof "report".

(d) SECTION 25.—Section 25(c) (7 U.S.C. 136w(c)) is amended—

(1) by inserting "or by regulation" after "hearing", and

(2) in paragraph (5), by striking out "prescribe regulations requiring" and inserting in lieu thereof "require".

SEC. 902. TECHNICAL AMENDMENTS.

(a) SECTION 2.—Section 2 (7 U.S.C. 136) is amended—

(1) in subsection (c), by striking out "if:" and inserting in lieu thereof "if—",

(2) in subsections (p)(2) and (u), by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services",

(3) in subsection (q)(2)(A), by striking out "if:" and inserting in lieu thereof "if—",

(4) in subsection (q)(2)(C)(iii), by striking out ": *Provided*, That" and inserting in lieu thereof ", except that",

(5) by striking out in subsection (u) ": *Provided*, That" and inserting in lieu thereof ", except that", by striking out "(1)(a)", by striking out "or (b)", by striking out "(2) that" and inserting in lieu thereof "that", and by striking out "an article covered by clause (1) of this proviso" and inserting in lieu thereof "a new animal drug", and

(6) by striking out in subsection (ee) ": *Provided*, That the term" and inserting in lieu thereof ", except that the term", by striking out "or" before clause (4), by striking out ": *Provided further*, That the term also shall not include" and inserting in lieu thereof ", (5)", by striking out "or any use" and inserting in lieu thereof "or (6) any use", and by striking out ": *And provided further*, That after" and inserting in lieu thereof a period and "After".

(b) SECTION 3.—Section 3 (7 U.S.C. 136a) is amended—

(1) by striking out ": *Provided*, That such" in subsection (c)(1)(D)(i) and inserting in lieu thereof a period and "Such",

(2) by striking out the semicolons at the end of clauses (i), (ii), and (iii) of subsection (c)(1)(D) and inserting in lieu thereof a period, by striking out "except as" in subsection (c)(1)(D)(ii) and inserting in lieu thereof "Except as", and by striking out "after expiration" in subsection (c)(1)(D)(iii) and inserting in lieu thereof "After expiration",

(3) in subsection (c)(1)(D), by striking out "subsection (c)(2)(D) of this section" and inserting in lieu thereof "paragraph (2)(D)",

(4) in subsection (c)(1)(D)(ii), by striking out "subparagraph (D)(i) of this paragraph" and inserting in lieu thereof "clause (i)",

(5) in subsection (c)(1)(D)(iii), by striking out "subparagraphs (D)(i) and (D)(ii) of this paragraph" and inserting in lieu thereof "clauses (i) and (ii)",

(6) by striking out ": *Provided*, That the" in subsection (c)(2)(B)(iv) and inserting in lieu thereof a period and "The",

(7) in subsection (c)(2)(B)(v), by striking out "subsection (c)(1)(D) of this section" and inserting in lieu thereof "paragraph (1)(D) of this subsection",

(8) by striking out "subsection (c)(5) of this section" in subsection (c)(7) each place it occurs and inserting in lieu thereof "paragraph (5)" and by striking out ": *Provided*, That if" in subsection (c)(7)(A) and inserting in lieu thereof a period and "If",

(9) by striking out ", provided that if" in subsection (d)(1)(A) and inserting in lieu thereof a period and "If" and by striking out ": *Provided, however*, That the" in such subsection and inserting in lieu thereof a period and "The",

(10) in subsection (d)(1)(C)(ii), by amending the last sentence to read as follows: "Any such regulation shall be reviewable in accordance with section 16(e).", and

(11) by striking out ": *Provided*, That as" in subsection (f)(2) and inserting in lieu thereof a period and "As".

(c) SECTION 4.—Section 4 (7 U.S.C. 136b) is amended—

(1) in subsection (a)(1), by striking out ": *Provided, however,* That the" and inserting in lieu thereof a period and "The", and

(2) by striking out ": *Provided,* That such" in subsection (c) and inserting in lieu thereof a period and "Such".

(d) SECTION 5.—Section 5(g) (7 U.S.C. 136c(g)) is amended by striking out ": *Provided,* That such" and inserting in lieu thereof a period and "Such".

(e) SECTION 6.—Section 6 (7 U.S.C. 136d) is amended—

(1) in subsection (c), by striking out "Agency" each place it occurs and inserting in lieu thereof "Administrator",

(2) in subsection (c)(1), by running into the second sentence the undesignated paragraph in that subsection,

(3) in subsection (c)(3), by striking out "(i)" and inserting in lieu thereof "(A)" and by striking out "(ii)" and inserting in lieu thereof "(B)", and

(4) in subsection (e)(2), by striking out ": *Provided*, That the" and inserting in lieu thereof a period and "The".

(f) SECTION 10.—Section 10 (7 U.S.C. 136h) is amended—

(1) by striking out ": *Provided*, That the" in subsection (d)(1) and inserting in lieu thereof a period and "The",

(2) by striking out ": *Provided further*, That this" in subsection (d)(1) and inserting in lieu thereof a period and "This", and

(3) by striking out ": *Provided*, That where" in subsection (d)(3) and inserting in lieu thereof a period and "Where".

(g) SECTION 12.—Section 12(a)(2)(F) is amended by striking out ": *Provided,* That it" and inserting in lieu thereof a period and "It".

(h) SECTION 13.—Section 13 (7 U.S.C. 136k) is amended—

(1) in subsection (b), by taking the last sentence in paragraph (3) and inserting it after such paragraph as a full measure sentence, and

(2) in subsection (c), by striking out ": *Provided*, That upon" and inserting in lieu thereof a period and "On".

(i) SECTION 15.—Section 15(a) (7 U.S.C. 136m(a)) is amended by striking out "(i)" and "(ii)".

(j) SECTION 16.—Subsection (a) of section 16 (7 U.S.C. 136n) is amended to read as follows:

"(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to agency discretion by law are judicially reviewable by the district courts of the United States.".

(k) SECTION 17.—Section 17 (7 U.S.C. 136o) is amended—

(1) by striking out ": *Provided*, That the" in subsection (c) and inserting in lieu thereof a period and "The", and

(2) by striking out ": *And provided further,* That all" in subsection (c) and inserting in lieu thereof a period and "All".

(l) SECTION 18.—The heading for section 18 (7 U.S.C. 136p) is amended by inserting "**AND STATE**" after "**FEDERAL**" and by running in the second sentence after the first sentence.

(m) SECTION 19.—Section 19(a) (7 U.S.C. 136q(a)) is amended by striking out "canceled under section 6(c)" and inserting in lieu thereof "suspended under section 6(c) and canceled".

(n) SECTION 21.—Section 21 (7 U.S.C. 136s) is amended—

(1) by inserting "SECRETARY OF AGRICULTURE.—" before "The" in subsection (a),

(2) by inserting "VIEWS.—" after "(b)", and

(3) by inserting "NOTICE.—" after "(c)".

(o) SECTION 24.—Section 24 (7 U.S.C. 136v) is amended—

(1) by inserting "STATE REGULATION.—" after "(a)",

(2) by inserting "UNIFORMITY.—" after "(b)", and

(3) by inserting "ADDITIONAL USES.—" after "(c)".

(p) SECTION 25.—Section 25 (7 U.S.C. 136w) is amended—

(1) in subsection (a)(3), by striking out "Committee on Agriculture and Forestry" and inserting in lieu thereof "Committee on Agriculture, Nutrition, and Forestry", and

(2) in subsection (e), by striking out ": *Provided*, That whenever" and inserting in lieu thereof a period and "Whenever".

(q) SECTION 26.—Section 26 (7 U.S.C. 136w-1) is amended—

(1) by inserting "IN GENERAL.—" after "(a)" in subsection (a),

(2) by inserting "SPECIAL RULES.—" after "(b)" in subsection (b),

(3) by inserting "ADMINISTRATOR.—" after "(c)", and

(4) in subsection (a)(1), by striking out "; *Provided*, That the" and inserting in lieu thereof ", except that the".

(r) SECTION 27.—Section 27 (7 U.S.C. 136w-2) is amended—

(1) by inserting "REFERRAL.—" after "(a)",

(2) by inserting "NOTICE.—" after "(b)", and

(3) by inserting "CONSTRUCTION.—" after "(c)".

SEC. 903. TABLE OF CONTENTS AMENDMENTS.

The table of contents contained in section 1(b) (7 U.S.C. prec. 121) is amended—

(1) by striking out the item relating to section 2(e) and inserting in lieu thereof the following:

"(e) Applicator.
"(1) Commercial applicator.
"(2) Private applicator.
"(3) Certified applicator.
"(4) Under the direct supervision of a certified applicator.";

(2) by adding at the end of the items relating to section 2 the following:

"(ff) Outstanding data requirement.
"(1) In general.
"(2) Factors.
"(gg) Antimicrobial.
"(hh) Pesticide testing facility.
"(ii) Importing country.
"(jj) Pesticide dealer.
"(kk) To distribute or sell.";

(3) by striking out the item relating to section 3(a) and inserting in lieu thereof the following:

"(a) Requirement of registration.";

(4) by striking out the item relating to section 3(c)(8) and inserting in lieu thereof the following:

"(8) Public interim administrative review.

"(A) In general.
"(B) Criteria for initiating a public interim administrative review.
"(C) Review requirement.
"(D) Prereview notice procedures.
"(E) Notice.
"(F) Review procedure.
"(G) Judicial review.";

(5) by adding at the end of the items relating to section 3(c) the following:

"(9) Preregistration access to data.";

(6) by amending the item relating to section 3(g) to read as follows:

"(g) Priority list and data requirements for inert ingredients.
"(1) Establishment of list.
"(2) Publication of list.
"(3) Judicial review.
"(4) Number of ingredients.
"(5) Additional data.
"(6) Evaluation.
"(7) Construction.";

(7) by inserting after the items relating to section 3 the following:

"Sec. 3A. Reregistration of registered pesticides.
"(a) General rule.
"(b) Special authorities of Administrator.
"(1) Guidelines.
"(2) Monitoring.
"(3) Suspensions and penalties.
"(c) Reregistration phases.
"(d) Phase one.
"(1) Priority for reregistration.
"(2) Reregistration lists.
"(3) Judicial review.
"(4) Notice to registrants.
"(e) Phase two.
"(1) In general.
"(2) Notice of intent to seek or not to seek reregistration.
"(3) Missing or inadequate data.
"(4) Time periods.
"(5) Cancellation and removal.
"(f) Phase three.
"(1) Information about studies.
"(2) Time periods.
"(3) Cancellation.
"(g) Phase four.
"(1) Independent review and identification of outstanding data requirements.
"(2) Time periods.
"(h) Phase five.
"(1) Data review.
"(2) Reregistration and other actions.
"(i) Compensation of data submitter.
"(j) Fees.
"(1) Initial fee for food or feed pesticide active ingredients.
"(2) Final fee for food or feed pesticide active ingredients.
"(3) Fees for other pesticide active ingredients.
"(4) Reduction or waiver of fees for minor use and other pesticides.
"(5) Other fees.
"(6) Apportionment.
"(k) Exemption of certain registrants.
"(l) Reregistration fund.

"(m) Judicial review.";

(8) by adding at the end of the items relating to section 4 the following:

"(d) Provisions regarding commercial applicators.
"(e) Provisions regarding private applicators.
"(f) Recertification and reregistration.
"(g) Training material.
"(h) Minimum standards for trainers and training programs.
"(i) Privately administered training programs.
"(j) Enforcement officer training.
"(k) Separate standards.
"(l) State agency defined.";

(9) by striking out the items relating to section 6(a)(1) and 6(a)(2);

(10) by striking out the item relating to section 6(b) and inserting in lieu thereof the following:

"(b) Cancellation and change in classification or labeling.
"(1) Notice of cancellation or change in classification.
"(2) Hearing.
"(3) Factors.
"(4) Label changes.";

(11) by amending the item relating to section 6(d) to read as follows:

"(d) Public hearings.";

(12) by striking out the item relating to section 6(f) and inserting in lieu thereof the following:

"(f) Hearing procedures after public interim administrative review.
"(1) General rule.
"(2) Request for hearing.
"(3) Procedures.
"(g) General provisions.
"(1) Voluntary cancellation
"(2) Publication of notice.
"(3) Existing stocks.
"(4) Additional information.
"(h) Suspension and cancellation of registration based on false or invalid data.
"(1) Notice.
"(2) Invalid data.
"(3) False data.
"(4) Hearing.
"(i) Judicial review.";

(13) by adding at the end of the items relating to section 7 the following:

"(e) Public right to know.
"(f) Information requests.";

(14) by striking out the items relating to section 8 and inserting in lieu thereof the following:

"Sec. 8. Records.
"(a) Authority to require records.
"(b) Limitations.
"(c) Records of applicators.
"(d) Records of pesticide dealers.
"(e) Access.
"(f) Information for employees.";

(15)(A) by amending the item relating to section 9(a) to read as follows:

"(a) Authority to enter, inspect, and copy.";

and

(B) by adding at the end of the items relating to section 9 the following:

"(d) Procedure.
"(e) Coordination.";

(16) by adding at the end of the items relating to section 10 the following:

"(h) Data disclosure to States.
"(1) In general.
"(2) Action for just compensation.
"(3) Required disclosure.";

(17) by striking out the items relating to section 11;

(18) by adding at the end of the items relating to section 12 the following:

"(c) Acts of officers, agents, etc.";

(19) by adding at the end of the items relating to section 14(a) the following:

"(6) Subpoenas.",

(20) by striking out the item relating to section 14(b)(4);

(21) by adding at the end of the items relating to section 15 the following:

"(c) Report.";

(22) by adding at the end of the items relating to section 16 the following:

"(e) Review of regulations.";

(23) by striking out the items relating to subsections (a) and (b) of section 17 and inserting in lieu thereof the following:

"(a) Pesticides and devices intended for export.
"(1) Violations.
"(2) Restricted use or unregistered pesticides.
"(3) Notification specifications.
"(4) Labels.
"(5) Records.
"(b) Notices of regulatory action furnished to foreign governments.
"(1) Issuance.
"(2) Contents.";

(24) by amending the item relating to section 18 to read as follows:

"Sec. 18. Exemption of Federal and State agencies.";

(25) by adding below the item relating to section 21 the following:

"(a) Secretary of Agriculture.
"(b) Views.
"(c) Notice.";

(26) by adding at the end of the items relating to section 22 the following:

"(c) Effect on certain other laws.";

(27) by adding below the item relating to section 24 the following:

"(a) State regulation.
"(b) Uniformity.
"(c) Additional uses.";

(28) by adding at the end of the items relating to section 25(a) the following:

"(4) Congressional review of regulations.";

(29) by adding at the end of the items relating to section 25 the following:

"(e) Peer review.
"(f) Worker health and safety.";

(30) by adding below the item relating to section 26 the following:

"(a) In general.
"(b) Special rules.
"(c) Administrator.
"(d) Expiration.";

(31) by adding below the item relating to section 27 the following:

"(a) Referral.
"(b) Notice.
"(c) Construction.";

and

(32) by striking out the item relating to section 31 and inserting in lieu thereof the following:

"Sec. 31. Collection, dissemination, and use of data.
"(a) Data systems.
"(b) Data retrieval.
"(c) Index.
"(d) Report.
"(e) Confidentiality.
"(f) Authorization.
"Sec. 32. Groundwater authority.
"(a) In general.
"(b) Use of other authorities.
"(c) Consultation with States.
"(d) Consultation with Secretary of Agriculture.
"Sec. 33. Authorization for appropriations.".

TITLE X—EFFECTIVE DATE

SEC. 1001. EFFECTIVE DATE.

Except as otherwise provided in this Act, the amendments made by this Act shall take effect upon the expiration of 60 days after the date of enactment of this Act.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

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SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

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(b) TABLE OF CONTENTS.—

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(b) Table of contents.
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(c) Adulterated.
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* * * * * * *

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[Sec. 8. Records.
(a) Authority to require records.
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(c) Records of applicators.
(d) Records of pesticide dealers.
(e) Access.
(f) Information for employees.
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* * * * * * *
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(a) Pesticides and devices intended for export.
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* * * * * * *
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* * * * * * *
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* * * * * * *

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(a) Data systems.
(b) Data retrieval.
(c) Index.
(d) Report.
(e) Confidentiality.
(f) Authorization.
Sec. 32. Groundwater authority.
(a) In general.
(b) Use of other authorities.
(c) Consultation with States.
(d) Consultation with Secretary of Agriculture.
Sec. 33. Authorization for appropriations.

SEC. 2. DEFINITIONS.

For purposes of this Act—

(a) * * *

* * * * * * *

(c) ADULTERATED.—The term "adulterated" applies to any pesticide [if]: *if*—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

* * * * * * *

[(e) CERTIFIED APPLICATOR, ETC.—

[(1) CERTIFIED APPLICATOR.—The term "certified applicator" means any individual who is certified under section 4 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

[(2) PRIVATE APPLICATOR.—The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

[(3) COMMERCIAL APPLICATOR.—The term "commercial applicator" means an applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

[(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.]

(e) APPLICATOR.—

(1) COMMERCIAL APPLICATOR.—

(A) Except as provided in subparagraph (B), the term "commercial applicator" means a person (whether or not the person is a private applicator with respect to some uses) who—

(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use,

(ii) uses or supervises the use of any pesticide for hire as the principal part of the person's business or work, or

(iii) as an employee of a person described in clause (ii) uses or supervises the use of any pesticide.

(B) The term does not include a person who uses or supervises the use of pesticide as described in paragraph (2).

(2) PRIVATE APPLICATOR.—The term "private applicator" means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity—

(A) on property owned or rented by such person or such person's employer, or

(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) CERTIFIED APPLICATOR.—The term "certified applicator" means a commercial or private applicator who is certified under section 4.

(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is used.

* * * * * * *

[(n) INGREDIENT STATEMENT.—The term "ingredient statement means a statement which contains—

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[(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

[(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.]

(n) INGREDIENT STATEMENT.—The term "ingredient statement" means a statement that contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in a pesticide,

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic,

(2) the name of each inert ingredient in the pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the use pattern and concentration level of the inert ingredient in the pesticide,

(3) if the pesticide contains arsentic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic,

(4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement that the nature of the active ingredient is accurately represented, and

(5) the name of any inert ingredient for which the Administrator has required additional data under section 3(g)(5) because such ingredient is listed under section 3(g)(1)(A) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8).

* * * * * * *

(p) LABEL AND LABELING.—

(1) LABEL.—The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) LABELING.—The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) Accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of [Health, Education, and Welfare] *Health and Human Services,* State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) MISBRANDED.—

(1) A pesticide is misbranded if—

(A) * * *

* * * * * * *

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; [or]

(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America [.]; *or*

(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label is not written in an appropriate language as required by section 17(a)(4)(A) or does not contain the same health, safety, and hazard precautions as a pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country.

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on the part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph [if:] *if—*

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

* * * * * * *

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) * * *

* * * * * * *

(iii) the net weight or measure of the content[: *Provided,* That], *except that* the Administrator may permit reasonable variations; and

* * * * * * *

(u) PESTICIDE.—The term "pesticide" means (1) any substance or mixture or substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant [: *Provided,* That], *except that* the term "pesticide" shall not include any article [(1)(a)] that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), [or (b)] that has been determined by the Secretary of [Health, Education, and Welfare] *Health and Human Services* not to be a new animal drug by a regulation establishing conditions of use for the article, *and (3) any substance or mixture of substances intended for a purpose described in subsection (gg),* or [(2)] that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing [an article covered by clause (1) of this proviso.] *a new animal drug.*

* * * * * * *

(bb) UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT.—The term "unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. *For purposes of this subsection, the term "man" includes unborn human beings from the moment of conception.*

* * * * * * *

(ee) TO USE ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING.—The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling[: *Provided,* That], *except that* the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling *unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency,* (2) applying a pesticide against any target pest not specified on the labeling if the application is to crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling, [or] *unless the labeling specifically states that the product may be applied only by the methods specified on the labeling,* (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling[: *Provided further,* That the term also shall not include], *(5)* any use of a pesticide in conformance with section 5, 18, or 24 of this Act, or *(6)* any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act[: *And provided further,* That after]. *After* March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of

the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) OUTSTANDING DATA REQUIREMENT.—

(1) IN GENERAL.—The term "outstanding data requirement" means a requirement for any study, information, or data which is necessary to make a determination under section 3(c)(5) and which study, information, or data—

(A) has not been submitted to the Administrator, or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 3(c)(5) and the regulations and guidelines issued thereunder, as determined by the Administrator.

(2) FACTORS.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) ANTIMICROBIAL.—The term "antimicrobial" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air,

(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture,

(3) disinfectants intended to destroy or irreversibly inactive bacteria, fungi, or viruses on surfaces or inanimate objects, or

(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces.

(hh) PESTICIDE TESTING FACILITY.—The term "pesticide testing facility" means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing it). The term does not include any person solely on account of such person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit under section 5.

(ii) IMPORTING COUNTRY.—The term "importing country" means the first country to which a pesticide, device, or active ingredient, subject to the notification requirements of section 17(a), is exported from the United States.

(jj) PESTICIDE DEALER.—

(1) Except as provided in paragraph (2), the term "pesticide dealer" means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or designated under section 8(d)(2).

(2) Such term does not include a person who only distributes or sells pesticides that are classified for general use and that are not designated under section 8(d)(2).

(kk) TO DISTRIBUTE OR SELL.—The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticide products or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

SEC. 3 REGISTRATION OF PESTICIDES.

[(a) REQUIREMENT.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator.]

(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.

* * * * * * *

(c) PROCEDURE FOR REGISTRATION.—

(1) STATEMENT REQUIRED.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) * * *

* * * * * * *

(D) except as otherwise provided in [subsection (c)(2)(D) of this section *paragraph (2)(D),* if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide[: *Provided,* That such]. *Such* permission shall not be required in the case of defensive data[;].

(ii) [except] *(I) Except* as otherwise provided in [subparagraph (D)(i) of this paragraph] *clause (i),* with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, [or for reregistration,] *for reregistration, or to support the safety of an inert ingredient* the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application *or in support of the safety of an inert ingredient* by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, [binding arbitration] under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in

support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation [;].

(II) If the term of a patent for a pesticide registered under this section is extended after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 under an Act of Congress that amends title 35, United States Code, to authorize an extension of the term of a patent for a pesticide that had not expired before the date of enactment of such Act of Congress irrespective of the date the pesticide completed a regulatory review period as defined in such title, the amount of compensation to be paid under arbitration under subclause (I) for the use of data submitted to the Administrator for such pesticide shall be a fair share of the cost of producing the data plus a value premium not to exceed that share, as determined in the arbitration process.

(III) In the case of a pesticide the term of the patent for which has expired, the terms and amount of compensation, for data that was submitted for such pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data may be fixed before the submission of such application by arbitration under subclause (I) initiated by such person. The arbitration shall be binding on the original data submitter and shall be binding on such person after the date such person's application is submitted. Each party to the first arbitration under this subclause to determine the terms and amount of compensation for the use of particular data shall share equally in the payment of the fees and expenses of the arbitrators and shall each pay its own attorney's fees. In all subsequent arbitrations under this subclause to determine the terms and amount of compensation for

the use of such data, the party to such subsequent arbitration who seeks to cite the data of the original data submitter shall pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter. The provisions of subclause (I) apply to arbitrations under this clause, except as otherwise provided in this subclause.

(iii) [after] *After* expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under [subparagraphs (D)(i) and (D)(ii) of this paragraph] *clauses (i) and (ii),* the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data[;].

* * * * * * *

(2)(A) DATA IN SUPPORT OF REGISTRATION.—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph *including information regarding an inert ingredient in a pesticide,* he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATION.—

(i) * * *

[(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to

examine and rely upon such data in support of maintenance of such registration.]

(ii)(I) Each registrant of a pesticide for which a notice is issued under clause (i) shall provide evidence within 90 days after receipt of such notification that it is taking appropriate steps to secure the additional data that are required under such notice.

(II) Each registrant of a pesticide that contains an active ingredient that is only used for application in the production of food, feed, or fiber shall, by the ninetieth day after notification, agree to develop jointly the additional data concerning that active ingredient that are required under such notice or to share in the cost of developing, such data and advise the Administrator of their intent. Any such registrant who agrees to develop jointly, or to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

(IV) If a pesticide contains active ingredients that are used for application on food, feed, or fiber and for other purposes, the registrants of the pesticide who are subject to a requirement to submit additional data shall be subject to subclause (II) or (III), whichever the majority of the registrants of the pesticide shall agree to.

(iv) Notwithstanding any other provisions of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to particpate in a procedure for reaching agreement concerning a joint data development arrangement under the subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph or a registrant failed to take an action required under clause (ii)(II), the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act[: *Provided,* That

the]. *The* only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provisions of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of [subsection (d)(1)(D) of this section.] *paragraph (1)(D) of this subsection.* Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for joint submitters of such data.

* * * * * *

[(D) EXEMPTION.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

[(i) submit or cite data pertaining to the safety of such purchased product; or

[(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.]

(D) EXEMPTION.—

(i) No applicant for registration or amended registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(I) submit or cite data pertaining to such purchased pesticide, or

(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data.

(ii) No applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person in order to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study concerning such ingredient if any por-

tion of the cost of the study will be or could be included in the price of the purchased ingredient.

* * * * * * *

(4) NOTICE OF APPLICATION.—The Administrator shall publish in the Federal Register, [promptly] *not later than 30 days* after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. [The] *Except as provided in paragraph (a), the* notice shall provide for a period of [30] *60* days in which any Federal agency or any other interested person may comment.

* * * * * * *

(6) DENIAL OF REGISTRATION.—If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6[.] *except as otherwise provided in this paragraph. A request for a hearing under section 6 shall be made within 30 days after the receipt of such notification. The Administrator may issue regulations governing the right to a hearing under section 6 with regard to the denial of any application for the registration of a product containing an ingredient that was cancelled under section 6. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings. Section 6(g)(2) applies with respect to the publication of a notice of a denial of a registration.*

(7) REGISTRATION UNDER SPECIAL CIRCUMSTANCES.—Notwithstanding the provision of [subsection (c)(5) of this section] *paragraph (5)*—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the appli-

cant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit *or cite* such data as would be required to obtain registration of a similar pesticide under [subsection (c)(5) of this section: *Provided,* That, if] *paragraph (5). If* the applicant is unable to submit *or cite* an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission *or citation* of such data not later than the time such data are required to be submitted *or cited* with respect to similar pesticides already registered under this Act.

[(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provision of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations, issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves as minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section: *Provided,* That, if the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

[(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient

for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe: *Provided,* That a conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.]

(B)(i) The Administrator may conditionally amend the registration of a pesticide under this Subparagraph to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

(I) the applicant has submitted or cited the additional data that the Administrator may require solely for the proposed additional use,

(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment, and

(III) the additional use is in the public interest.

(ii)(I) Except as provided in subclause (II), if the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), no registration of the pesticide may be amended under clause (i) to add any food or feed use during the pendency of any evaluation by the Administrator initiated by such notice.

(II) If the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), the Administrator may amend the registration of the pesticide under clause (i) to add a minor food or feed use if the Administrator detemines, with the concurrence of the Secretary of Agriculture, that there is not available an effective alternative pesticide that does not meet or exceed such risk criteria.

(iii) An applicant seeking an amended registration of a pesticide under this subparagraph shall submit or cite to the Administrator such data as would be required to obtain a registration of a similar pesticide under paragraph (5). Except as provided in clause (iv), if the applicant is unable to submit or cite an item of such data because it has not yet been generated, the Administrator may amend the registration of the pesticide under such conditions as will require the submission or citation of such data not later than the time such data are required to be submitted for the mainte-

nance of a registration of the similar pesticide under this section.

(iv) If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide and if a period reasonably sufficient for the generation and submission of such data has elapsed since the Administrator first imposed the data requirement, a conditional amendment to permit an additional use of the pesticide for other than a minor use shall not be granted under clause (i) unless such data have been submitted.

(C)(i) Except as provided in clauses (ii) and (iii), the Administrator may conditionally register a pesticide under this subparagraph containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data that have not been submitted because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement (I) on the conditions that by the end of such period the Administrator receives such data and that the data that the Administrator receives do not meet or exceed risk criteria enumerated in regulations issued under paragraph (8), and (II) on such other conditions as the Administrator may prescribe.

(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

(I) use of the pesticide during the period referred to in clause (i) will not cause any unreasonable adverse effect on the environment, and

(II) use of the pesticide is in the public interest.

(iii) The Administrator shall not conditionally register a pesticide under this subparagraph if data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of such a pesticide under paragraph (5), a period reasonably sufficient for generation of such data has elapsed since the Administrator first imposed the data requirement, and such data have not been submitted to the Administrator.

[(8) INTERIM ADMINISTRATIVE REVIEW.—Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.]

(8) PUBLIC INTERIM ADMINISTRATIVE REVIEW PROCEEDINGS.—

(A) IN GENERAL.—A public interim administrative review process to determine whether the use of a pesticide (including a category of pesticides) may cause unreasonable adverse effects to the environment shall be conducted in accordance with this paragraph.

(b) CRITERIA FOR INITIATING A PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(i) Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

(ii) Such criteria shall be established on the basis of levels of risk and may include consideration of currently available exposure data.

(iii) Absence of exposure data shall not delay or preclude initiation of a public interim administrative review. The Administrator may decline to initiate a public interim administrative review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

(c) REVIEW REQUIREMENT.—The Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of such pesticide required under this Act unless such public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

(d) PRE-REVIEW NOTICE PROCEDURES.—

(i) On receipt of information respecting a pesticide demonstrating that the criteria for initiating a public interim administrative review established under subparagraph (B) have been met, the Administrator shall immediately notify all registrants of such pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met.

(ii) Not late than 30 days after receipt of such notice provided under clause (i), a registrant may respond to such notice.

(iii) Not late than 60 days after the Administrator provided a notice under clause (i) concerning a pesticide, the Administrator shall determine whether a public interim administrative review of the pesticide shall be initiated.

(e) NOTICE.—If the Administrator intends to initiate a public interim administrative review of a pesticide that is registered for agricultural uses, the Administrator shall notify the Secretary of Agriculture of the intention to initiate such review and the reasons therefor.

(f) REVIEW PROCEDURE.—

(i) Any public interim administrative review proceeding shall be initiated and conducted in accordance with regulations published by the Administrator. Such

regulations shall provide that a public interim administrative review shall include—

(I) a notice of initiation of the public interim administrative review and opportunity for public comment on such notice,

(II) a notice of a preliminary determination and opportunity for public comment on such notice, and

(III) a notice of a final determination,

except that such regulations may authorize the Administrator to combine or forgo any such notice.

(ii) Any proposed determination of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at its next scheduled meeting for comment solely on relevant scientific issues. The public may submit comments to the Scientific Advisory Panel concerning such issues.

(iii) The notice of the initiation of a public interim administrative review or the notice of a preliminary determination shall state the basis for such review or determination and include a request for any additional data needed and a bibliography of all scientific data and studies and expert analyses concerning the risks or benefits of the pesticide that are under review. Information in the bibliography shall be made available to the public consistent with the requirements of section 10. The Administrator shall determine, to the extent feasible, before the initiation of the public interim administrative review which data in the bibliography may be disclosed to the public under section 10(d)(1). If the Administrator receives additional data concerning such risks or benefits, the Administrator, within 30 days of receiving the additional data, shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

(iv) Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments may be submitted on such review or determination. Any person who submits comments shall disclose to the Administrator all scientific data and studies and expert analyses in such person's possession concerning the risks or benefits of the pesticide that are under review that were not included in the bibliography included in such notice. If such person receives additional scientific data or studies or expert analyses of such data or studies that were not included in such bibliography, the person shall disclose such scientific data, studies, and expert analysis to the Administrator within 30 days after receipt.

(v) Not later than 18 months after the initiation of a review, the Administrator shall decide which regulatory action (if any) to take regarding the pesticide that

is the subject of the review and shall publish the decision.

(vi) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

(I) additional data critical to a fair and accurate determination of risks posed by the pesticide subject to review are required,

(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year, and

(III) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for such data at such time.

(g) JUDICIAL REVIEW.—Any person may seek judicial review under section 16(a) of the failure of the Administrator to act within the time period prescribed under this paragraph.

(9) PREREGISTRATION ACCESS TO DATA.—

(A) If an application for—

(i) a registration of a pesticide containing a new active ingredient, or

(ii) a registration of a pesticide to authorize the initial food use of a pesticide active ingredient,

is submitted to the Administrator, the Administrator, before acting on such application, shall provide, in accordance with this paragraph, public access to health, safety, and environmental data that are submitted or cited in support of such application.

(B) To obtain access to the data referred to in subparagraph (A), a person shall send by certified mail—

(i) not later than 30 days after the publication under paragraph (4) of a notice of the application referred to in subparagraph (A), and

(ii) simultaneously to the Administrator and to the applicant for the registration of the pesticide,

a request for such access and the affirmation required by subparagraph (D).

(C)(i) Unless within 15 days after the Administrator's receipt of a request for access to such data and of an affirmation complying with subparagraph (D) the applicant submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and the reasons for the objection, the Administrator shall grant the request. If an objection to a request is submitted to the Administrator within such 15-day period, the Administrator shall determine whether to grant the request within 5 days after the receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the applicant making the objection has been notified that access has been granted.

(ii) If access to data is denied under clause (i), comments on the application for which such data were submitted or cited shall be filed within 60 days after the decision of the Administrator denying access.

(D)(i) Data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) containing the information prescribed by clause (ii).

(ii) The affirmation required under clause (i) shall—

(I) state that the person in not engaged in, and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate thereof engaged in the production, sale, or distribution of a pesticide,

(II) identify any business, employer, or other person, if any, on whose behalf the person is requesting access to the data, and

(III) state that the person will not intentionally or recklessly violate this paragraph.

For purposes of this clause, an affiliate of a person is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the person.

(iii) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

(E)(i) Data supporting an application may be made available under subparagraph (A) to a person only for the purpose of permitting the person to comment to the Administrator on such application. Such comments may reasonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(ii) Except as provided in clause (iii), a person who obtains data under subparagraph (A) (directly or indirectly) may not—

(I) publish copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world, or

(II) use the data for any purpose in any court or agency of the United States or any State or political subdivision thereof before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(iii) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide for which such data were submitted.

(F)(i) Data made available under this paragraph may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions

prescribed by this paragraph and may not be removed from such office.

(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent to the data submitter on request.

(G) Once access to data respecting an application is granted, the data may be examined and notes may be taken for use in developing comments on the application. Such comments on the application shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator for an additional 30 days for good cause.

(d) CLASSIFICATION OF PESTICIDES.—

(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use, [provided that if]. *If* the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation [on the initial classification] and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses[: *Provided, however,* That the]. *The* Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

* * * * * * *

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted [use:] *use.*

[(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.]

[(ii)] If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. [Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.] *Any such regulation shall be reviewable in accordance with section 16(e).*

* * * * * * *

(f) MISCELLANEOUS.—

(1) EFFECT OF CHANGE OF LABELING OR FORMULATION.—If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.

(2) REGISTRATION NOT A DEFENSE.—In no event shall registration of an article be construed as a defense for the commission of any offense under this Act[: *Provided,* That as]. *As* long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

* * * * * * *

[(g) REREGISTRATION OF PESTICIDES.—The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided,* That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.]

(g) PRIORITY LIST OF DATA REQUIREMENTS FOR INERT INGREDIENTS.—

(1) ESTABLISHMENT OF LIST.—Subject to paragraph (4), the Administrator shall establish a priority list of inert ingredients consisting of—

(A) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8),

(B) inert ingredients (i) for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, (ii) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect, and (iii) that have significant use in pesticides or to which there is significant exposure from pesticides, and

(C) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment and to which there is significant exposure from pesticides.

(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

(3) JUDICIAL REVIEW.—The priority list under paragraph (1), the inclusion or exclusion of an ingredient on or from the priority list, and any revision of the priority list shall not be subject to judicial review.

(4) NUMBER OF INGREDIENTS.—The priority list under paragraph (1) shall consist of not less than 50 inert ingredients unless the Administrator determines that there is not a sufficient number of inert ingredients meeting the requirements for listing under paragraph (1) to reach such minimum number. Such list may not exceed 75 inert ingredients.

(5) ADDITIONAL DATA.—

(A) The Administrator shall determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list under paragraph (1). The Administrator shall require submission of such data from each registrant of such pesticide under this Act or from manufacturers and processors of the inert ingredient under the Toxic Substances Control Act. Such data shall be submitted within a reasonable time but not later than 4 years after the date of the request. The Administrator may extend the period for the submission of data by not more than 2 years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the necessary data.

(B) Data requirements imposed under subparagraph (A) or a decision not to require data for an inert ingredient shall be subject to judicial review under section 16(b).

(6) EVALUATION.—Within 1 year after the receipt of additional data under paragraph (5) for an inert ingredient, the Administrator shall evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment caused by pesticides containing such inert ingredient. Under exceptional circumstances, the Administrator may extend the period for evaluation by not more than 1 year.

(7) CONSTRUCTION.—This subsection shall not be construed to affect the authority of the Administrator—

(A) to regulate under this Act impurities, contaminants, degradants, or other ingredients of pesticides that have not been deliberately added to the pesticides,

(B) to regulate under this Act any deliberate added inert ingredient that has not previously been used in a pesticide or a significant new use in a pesticide of a deliberately added inert ingredient,

(C) to require the submission of short-term, environmental fate, or residue studies for deliberately added inert ingredients, or

(D) to require the submission of revised formula statements under subsection (c)(2)(B).

SEC. 3A. REREGISTRATION OF REGISTERED PESTICIDES.

(a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements, and

(2) the requirements of section 3(c)(5) have been satisfied.

(b) SPECIAL AUTHORITIES OF ADMINISTRATOR.—

(1) GUIDELINES.—Not later than one year after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator by order shall issue guidelines to be followed by registrants in—

(A) summarizing studies,

(B) reformatting studies,

(C) identifying adverse information, and

(D) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section.

in accordance with subsection (f)(1). Guidelines issued under this paragraph shall not be subject to judicial review.

(2) MONITORING.—The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under this section.

(3) SUSPENSIONS AND PENALTIES.—

(A) The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if—

(i) the Administrator determines that progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under subsection (e)(3)(B) or (f)(1)(H) within the time period prescribed by subsection (e)(4)(B) or (f)(2)(B) or the registrant has not submitted such data to the Administrator within such time period.

(ii) The Administrator determines that tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under subsection (g)(1)(B)

(iii) the Administrator determines that progress is insufficient to ensure submission data referred to in clause (ii) within the time period prescribed by subsection (g)(2)(B) or the required data have not been submitted to the Administrator within such time period, or

(iv) a registrant fails to comply with clause (ii) or (iii) of section 3(c)(2)(B)

(B) A registrant who submits a certification under subsection (f)(1)(G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(c) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (d) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (e) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by the registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (f).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (g) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (h) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(d) PHASE ONE.—

(1) PRIORITY FOR REREGISTRATION.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986) that—

(A) are in use on or in food or feed and may result in postharvest residues,

(B) may result in residues of potential toxicological concern in potable groundeater, edible fish, or shellfish,

(C) have been determined by the Administrator before the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 to have significant outstanding data requirements, or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) REREGISTRATION LISTS.—For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list pesticide active ingredients for which registration standards have been issued before such date,

(B) not later than 4 months after the date of the enactment of the Federal Insecticide, Fungicide, and Rodenticide

Act Amendments of 1986, list the first 150 pesticide active ingredients, as determined under paragraph (1),

(C) not later than 7 months after the date of the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list the second 150 pesticide active ingredients, as determined under paragraph (1), and

(D) not later than 10 months after the date of the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) NOTICE TO REGISTRANTS.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (e) whether they intend to seek or not to seek reregistration of such pesticides.

(e) PHASE TWO.—

(1) IN GENERAL.—The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, agreement, or offer described in pargraph (3).

(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient,

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations, and

(iii) data identified under clause (i) that have not been submitted to the Administrator, and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B), or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (f)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) TIME PERIODS.—

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient,

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient, and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment order under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, upon application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice on expiration of such 60 days, the Administrator, by order and without a hearing may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B) If no registrant of a pesticide containing active ingredient listed under subsection (d)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient, if no such registrant complies with paragraph (3)(A), or if no such registrant makes a committment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A), or if the fee prescribed by subsection (j)(1) has not been paid with regard to the active ingredient, the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (d)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice. After the 60-day period has expired the Administrator by order may cancel any such registration without hearing, except that the Administration shall not cancel a registration under this subparagraph if—

(i) during the comment period a person acquires the registrant's rights in that registration,

(ii) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2), and

(iii) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by subsection (j)(1) has been paid.

(f) PHASE THREE.—

(1) INFORMATION ABOUT STUDIES.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) who has submitted a notice under subsection (e)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under subsection (b)(1), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide, on such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section,

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of

the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and regulations issued under such section but which the registrant asserts should be deemed to comply with such section and regulations,

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982,

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and sub-chronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section,

(E) an identification of data that are required to be submitted to the Administrator under section 6(g)(4) indicating an adverse effect of the pesticide,

(F) an identification of any other information available that in the registrant's view supports the registration,

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B),

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant, or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing, and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

(2) TIME PERIODS.—

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient,

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient, and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than

12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1) (H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such subparagraph. The Administrator, upon application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submissions to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submissions to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii) If the Administrator determines that the registrant did not make a good faith attempt to conform its submissions to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail. The registration shall be cancelled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant. If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to to conform its submissions such to guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(g) PHASE FOUR.—

(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQUIREMENTS.—

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (e)(3) and (f)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the Administrator's review under this section, the Administrator

may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (f)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

(2) TIME PERIODS.—

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 18 months after the date of the listing of such active ingredient,

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 24 months after the date of the listing of such active ingredient, and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, upon application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(h) PHASE FIVE.—

(1) DATA REVIEW.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (d)(2) and of all other available data found by the Administrator to be relevant.

(2) REREGISTRATION AND OTHER ACTIONS.—

(A) ELIGIBILITY FOR REREGISTRATION.—Within 1 year after the submission of data concerning on active ingredient a pesticide under subsection (g), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than one additional year.

(B) PRODUCT-SPECIFIC DATA.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after

its submission. The Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of particular data.

(c) REGISTRATION.—After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(d) OTHER ACTION.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(i) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (e), (f), (g), or (h) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall not be taken into account.

(j) FEES.—

(1) INITIAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $50,000 upon submission of information under paragraphs (2) and (3) of subsection (e) for such ingredient.

(2) FINAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000 (i) upon submission of information for such ingredient under subsection (f)(1) if data are reformatted under subsection (f)(1)(C), or (ii) upon submission of data for such ingredient under subsection (f)(2)(B) if data are not reformatted under subsection (f)(1)(C).

(B) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (A) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000 at such time as the Administrator shall prescribe.

(3) FEES FOR OTHER PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is not an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

(B) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (A) of subsection (d)(2) and that is not an active ingredient of any pesticide that is registered for a major use on food or feed shall collectively pay a fee of not more than $100,000 and not less than $50,000 at such time as the Administrator shall prescribe.

(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.—

(A) In the case of an active ingredient of a pesticide that is registered solely for an agricultural or non-agricultural minor use or in the case of a pesticide the value or volume of use of which is small, the Administrator, upon application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

(B) In the case of an antimicrobial active ingredient for which the production level does not exceed 1,000,000 pounds per year, the Administrator, upon application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

(C) In the case of a small business registrant that produces an active ingredient of a pesticide, the Administrator may, upon application and in the sole discretion of the Administrator, reduce or waive the fees prescribed by paragraph (3). For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

(i) has 125 or fewer employees, and

(ii) for the last 3 years, before application is made for a reduction or waiver, had an average annual gross revenue that did not exceed $20,000,000.

(5) OTHER FEES.—On payment of fees for the reregistration of a pesticide in accordance with paragraph (1), (2), (3), or (4), the Administrator may not levy any other fees for the reregistration with respect to that active ingredient.

(6) Apportionment.—If two or more registrants are required to pay any fee prescribed by this subsection with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the three calendar years preceding the date of payment of such fee. The Administrator, by order, may require such registrants to submit such reports as the Administrator determines to be

necessary to allow the Administrator to apportion fees under this paragraph. If any such report is not submitted by a registrant after receiving notice of such report requirement, on any fee prescribed by this subsection for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under paragraph (1), (2), or by 3(B) the Administrator may order and without hearing cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator then shall reapportion the fee among the remaining registrants and notify such registrants that they are required to pay to the Administrator any unpaid balance of the fee within 30 day after receipt of such notice.

(k) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (e), (f), (g), and (j) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(l) REREGISTRATION FUND.—

(1) There shall be established in the Treasury of the United States a revolving fund.

(2) All fees collected by the Administrator under subsection (j) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out this section.

(3) Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit,

(B) invested in obligations of the United States or guaranteed thereby, or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(4) The Administrator shall—

(A) provide an annual accounting of the fees collected and disbursed from the fund, and

(B) take all steps necessary to ensure that expenditures of such funds are used to carry out this section.

(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

SEC. 4. USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.

(a) CERTIFICATION PROCEDURES.—

(1) FEDERAL CERTIFICATION.—Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standard will provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification [: *Provided, however,* That the]. *The* certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his

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completing a certification form. The administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may *by regulation* require any pesticide dealer participation in a certification program to be licensed under a State licensing program approved by him.

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(c) INSTRUCTION IN INTEGRATED PEST MANAGEMENT TECHNIQUES.—Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a), and State plans submitted to the Administrator under susbections (a) and (b), shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 23(c) of this Act, but such plans may not require that any individual receive instruction concerning such techniques or be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified of the availability of such instructional materials. In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides[: *Provided,* That such] *Such* program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe.

(d) PROVISIONS REGARDING COMMERCIAL APPLICATORS.—

(1) It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is—

(A) a certified commercial applicator,

(B) a registered commercial applicator under the direct supervision of a certified applicator who is a certified commercial applicator.

(2) To be considered to be a certified commercial applicator, a person, at a minimum shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material referred to in subsection (g),

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

(iii) that satisfies the minimum standards for training programs prescribed under subsection (h),

(B) have had field, institutional, or industrial experience in pesticide use and application,

(C) have passed an examination prescribed by such State agency, and

(D) possess a valid commercial applicator certification issued by such State agency.

(3) To be considered to be a registered commercial applicator, a person, at a minimum shall—

(A) have received training—

(i) prescribed by the State agency, including training in the material referred to in subsection (g), and

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

(B) possess a valid registration issued by such State agency.

A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

(e) PROVISIONS REGARDING PRIVATE APPLICATORS.—

(1) A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if it is applied by a person who is either—

(A) a certified private applicator, or

(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

(2) To be considered to be a certified private applicator, a person, at a minimum shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material described in subsection (g),

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h), and

(iii) that satisfies the minimum standards for training prescribed under subsection (h), and

(B) possess a valid private applicator certification issued by such State agency.

(3) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction—

(A) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling, and

(B) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A) has been received.

(f) RECERTIFICATION AND REREGISTRATION.—Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the State agency of such State. Such period may not be more than 5 years. The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14. To be recertified, an applicator shall, at a minimum, meet the requirements of paragraphs (2)(A), (2)(B), and (2)(D) of subsection (d) or the requirements of paragraphs (1) and (2) of subsection (e). To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

(g) TRAINING MATERIAL.—The Administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling. Within 12 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator, in consultation with the Secretary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

(h) MINIMUM STANDARDS FOR TRAINERS AND TRAINING PROGRAMS.—

(1)(A) The Administrator shall establish within one year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986—

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d), and

(ii) minimum standards for the training programs referred to in subsection (d).

(B) Training programs prescribed by any State under subsection (d) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring its training program into compliance with such standards. If on expiration of such 90-day period, the State's training program does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

(2)(A) The Administrator shall establish within 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e), and

(ii) minimum standards for the training programs referred to in subsection (e).

(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring its training program into compliance with such standards. If on expiration of such 90-day period the State's training program does not meet such standards, the Administrator shall prescribe the training programs referred to in subsection (e) for use in such State.

(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.—A State agency may approve any privately administered training program that it determines meets—

(1) the requirements established under this section, or

(2) requirements established by the State agency, whichever are more stringent.

(j) ENFORCEMENT OFFICER TRAINING.—Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, as a minimum, includes training covering materials specified in subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

(k) SEPARATE STANDARDS.—In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

(l) STATE AGENCY DEFINED.—For purposes of this section, the term "State agency" means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforce-

ment responsibility or that does not have an agency designated under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.

SEC. 5. EXPERIMENTAL USE PERMITS.

(a) * * *

* * * * * * *

(g) EXEMPTION FOR AGRICULTURAL RESEARCH AGENCIES.—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require[: *Provided,* that such]. *Such* pesticide may be used only by such research agency or educational institution for purposes of experimentation.

SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS.—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or othr interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect[: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.]. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

[(1) PROCEDURE.—]

[(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.]

[(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

[(1) to cancel its registration or to change its classification to gether with the reasons (including the factual basis) for his action, or

[(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Adminstrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time afer such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.]

(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.—

(1) NOTICE OF CANCELLATION OR CHANGE IN CLASSIFICATION.—

(A) If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or, when used in accordance with widespread and commonly recognized practice, generally

causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

(i) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the action of the Administrator, or

(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

(B) A notice issued under subparagraph (A) shall be sent to each registrant of the pesticide with respect to which the notice is issued and shall be made public.

(C) In determining whether to issue a notice under subparagraph (A), the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

(D)(i) Not later than 60 days before sending a notice to a registrant or making public such notice under subparagraph (B), whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of the proposed notice under subparagraph (A) and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture shall provide comments on such notice and analysis to the Administrator within 30 days after receiving the copy of such notice.

(ii)(I) If the Secretary of Agriculture provides such comments in writing within 30 days after receiving the copy of such notice, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

(II) If the Secretary of Agriculture does not provide such comments in writing within 30 days after receiving the copy of such notice, the Administrator may notify the registrant and make public the notice at any time after such 30-day period.

(iii) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary of Agriculture.

(E) If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirements of notice to the Secretary of Agriculture prescribed by subparagraph (D) and submission to the Scientific Advisory Panel under section 25(d) and proceed in accordance with subsection (c).

(2) HEARING.—

(A) The action proposed in a notice issued under paragraph (1)(A) shall become final and effective at the end of 30 days after receipt by the registrant or publication of a notice issued under paragraph (1)(B), whichever occurs later, unless within that time—

(i) the registrant makes the necessary corrections, if possible, or

(ii) a request for a hearing is made by a person adversely affected by the notice.

(B) Whenever a request for a hearing is made, the request shall—

(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed, and

(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

(C) Any party to the proceeding may identify findings and conclusions in dispute.

(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

(E) On receipt of a request for a hearing from a person without an economic interest in the pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man or the environment.

(3) FACTORS.—In taking any action under paragraph (1), the Administrator shall—

(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restriction, and

(B) consider the impact of such action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.

(4) LABEL CHANGES.—

(A) The Administrator may notify the registrant of a pesticide of a label change proposed by the Administrator that may be made by rulemaking under subparagraph (B) and provide that the registrant may submit comments to the Administrator on such proposed change in the 30-day period beginning on the date of the receipt of such notice. If a registrant who is notified by the Administrator of a proposed label change notifies the Administrator that the registrant does not object to such change, such change shall take effect as prescribed by the Administrator. If a registrant who is notified by the Administrator of a proposed label change does not submit comments to the Administrator in such 30-day period, the Administrator shall send such registrant a second notice stating that, if such registrant does not submit any comments to the Administrator in the 30-day period beginning on the date the registrant receives the second notice, the registration of such registrant shall be cancelled without a hearing or further notice. The registration of a registrant who does not submit comments on a second notice within such 30-day period shall be can-

celled without a hearing or further notice. If in response to a notice under this subparagraph a registrant submits comments to the Administrator objecting to a proposed label change, the Administrator may proceed under subparagraph (B).

(B) The Administrator may require changes to the label of a pesticide by informal rulemaking under this paragraph unless the changes—

(i) are equivalent to a cancellation of a use,

(ii) render the product unmarketable, or

(iii) otherwise have a major economic impact on persons affected by such changes.

If the Administrator may not require changes to the label of a pesticide by informal rulemaking under this paragraph because of clause (i), (ii), or (iii), the Administrator may only require such changes by a proceeding authorized by other provisions of this Act.

(C) After the promulgation of a regulation under subparagraph (B), the Administrator shall notify each registrant of the pesticide subject to the regulation of the label change required by the regulation and provide a 30-day period for each registrant to apply to the Administrator for an amendment to the registration to comply with the regulation. If a registrant does not apply for such an amendment within such period, the Administrator shall issue a notice of intent to cancel the registration of such registrant in accordance with paragraph (2). For purposes of paragraph (2), such notice shall be deemed to have been issued under paragraph (1).

(D) A registrant or user of a pesticide subject to a regulation issued under subparagraph (B) may request a hearing under subsection (d) on such regulation in accordance with paragraph (2). The scope of the hearing shall be limited to—

(i) whether the pesticide complies with the regulation,

(ii) whether the regulation by its terms is applicable to such pesticide, and

(iii) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was promulgated, it would be unreasonable to require such pesticide to comply with the regulation.

(E)(i) Except as provided in clause (ii), in an action under 16(e) for review of a regulation issued under subparagraph (B), the court, upon request, shall postpone the effective date of the regulation until completion of the review action if the petitioner shows—

(I) a likelihood of success on the merits in such action, and

(II) that the implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner.

(ii) A court in a review action under section 16(e) shall not postpone the effective date of a regulation issued under subparagraph (B) if the Administrator shows that failure to implement the regulation before completion of the action would cause a risk of substantial harm to health or the environment.

(c) SUSPENSION.—

(1) ORDER.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard." The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the **[**Agency**]** *Administrator* on the question of whether an imminent hazard exists.

(2) EXPEDITE HEARING.—If no request for a hearing is submitted to the **[**Agency**]** *Administrator* within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the **[**Agency**]** *Administrator* agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) EMERGENCY ORDER.—Whenever the Administrator determines that an emergency exists that does not permit him to hold a hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, paragraph (2) shall apply except that **[**(i)**]***(A)* the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and **[**(ii)**]***(B)* no party other than the registrant and the **[**Agency**]** *Administrator* shall participate except that any person adversely affected may file briefs within the time allotted by the **[**Agency's**]** *Administrator's* rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 16(b).

(4) JUDICIAL REVIEW.—A final order on the question of suspension following a hearing shall be reviewable in accordance with Section 16 of this Act, notwithstanding the fact that any related cancellation proceedings have not been completed. Any

order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) PUBLIC HEARINGS [AND SCIENTIFIC REVIEW].—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. [Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective with competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act.] As soon as practicable after completion of the hearing [(including the report of the Academy) but not later than 90 days thereafter]

but not later than 18 months after issuance of the notice that gave rise to the hearing, the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. *The time period prescribed by the preceding sentence may be extended by the Administrator under extraordinary circumstances for not more than one year.* Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) CONDITIONAL REGISTRATION.—

(1) The Administrattor shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met [: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment].

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section[: *Provided,* That the]. *The* only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(1) GENERAL RULE.—Subsection (d), as modified by the special rules of paragraphs (2) and (3) of this subsection, shall govern any hearing under subsection (d) that results from the Administrator's final determination in a public interim administrative review proceeding under section 3(c)(8) that is initiated after January 1, 1987, that includes an opportunity for comment on a notice of preliminary determination issued in connection with

such review, and for which the time between the first public notice for such review under section 3(c)(8)(F) and the close of the last comment period provided for such review is not less than 180 days.

(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in such pesticide) following a public interim administrative review described by paragraph (1) may request, or intervene in, a hearing in the manner provided by subsection (b)(2)(B) within 30 days after such decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with section 3(c)(8)(F).

(3) PROCEDURES.—

(A) At the request of a party, the administrative law judge conducting the hearing may receive into evidence portions of the public interim administrative review record and other evidence if the party demonstrates that such portions of the record and other evidence are relevant and material to the disputed issues and are not unduly repetitious and a competent witness is made available to be crossexamined on all matters relating to such evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the public interim administrative review proceeding by the exercise of due diligence by the offering party shall not be admissible.

(B) The right of other parties to confront and cross-examine witnesses with respect to such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross examination is not unduly repetitious.

(C)(i) Not later than 120 days after the administrative law judge is appointed, prehearing matters shall be completed and the hearing shall commence.

(ii) The administrative law judge may establish a schedule for prehearing matters, including discovery and motions, and shall ensure that the hearing schedule is met. The administrative law judge shall issue such orders as are appropriate for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision.

(iii) Discovery shall be permitted after the expiration of 120 days after the appointment of the administrative law judge on a determination by the administrative law judge that (I) such discovery shall not in any way unreasonably delay the proceeding, (II) the information to be obtained is not otherwise obtainable, and (III) such information has significant probative value and is necessary to obltain relevant evidence needed to resolve a material issue in dispute.

(D) Any challenge to—

(i) the authority to issue, or

(ii) the procedural correctness of the issuance of,

any notice of intent to cancel or change classification or to any request for a hearing or motion to intervene shall be filed with the administrative new judge not later than 30 days before the commencement of the evidentiary phase of the hearing.

(E) Not later than 30 days before the hearing commences, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits that the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended on motion by a party.

(F) If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and when in the judgment of the administrative law judge it is necessary, may submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis such time limits as may be established by the administrative law judge.

(G) The administrative law judge shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that the schedule shall not prejudice the right of a party to present evidence. The person who requested a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

(H) A hearing conducted in accordance with this subsection shall be completed and the Administrator shall make a final decision within 300 days after the issuance of the notice that gave rise to the hearing. The time limit imposed by this subparagraph may not be extended, except in exceptional cirucmstances in which such extension is essential for a fair and accurate determination of pivotal central to the proceeding. In no event may such time limit be extended more than 180 days. Any other time limit imposed by this paragraph may be extended for good cause.

(I) Failure to complete a hearing and make a final decision within the time period prescribed by subparagraph (H) shall be grounds for a civil action in a district court of the United States seeking an order to establish a schedule requiring the prompt completion of the hearing, but shall not be grounds for termination of the hearing or for making a final decision respecting the pesticide that is the subject of the hearing.

(g) GENERAL PROVISIONS.—

(1) VOLUNTARY CANCELLATION.—A registrant at any time may request that any of its pesticide registrations be cancelled or be amended to delete one or more uses. Before acting on any such request, the Administrator shall publish in the Federal Register

a notice of the receipt of the request. Thereafter the Administrator may approve such a request.

(2) PUBLICATION OF NOTICE.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 3A, or a notice issued under the third sentence of subsection (b)(4)(A) shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) EXISTING STOCKS.—The Administrator may permit the continued use, the continued distribution or sale, or both, of existing stocks of a pesticide whose registration is cancelled under any provision of this Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

(4) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator. For purposes of this paragraph, the term 'information' includes factual information and expert opinion regarding risks or benefits.

(h) SUSPENSION AND CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

(1) NOTICE.—The Administrator shall immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if—

(A) before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by the registrant of the pesticide to the Administrator in support of such registration were invalid;

(B) the data referred to in subparagraph (A)—

(i) have not been replaced as of the effective date of such Act, or

(ii) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988; and

(C) such data are material to the registration.

(2) INVALID DATA.—If, after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator determines that invalid data are sub-

mitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

(A) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports, or

(B) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue notices of intent to suspend and cancel such registration.

(4) HEARING.—

(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on the date of receipt by the registrant of a notice issued under this subsection unless during such period a request for a hearing is made by a person adversely affected.

(B) A hearing under this paragraph shall be conducted in accordance with the procedures presented by subsection (c) or (d), as appropriate.

(C) In the case of a hearing held with respect to action proposed to be taken under paragraph (1), the only matters for resolution shall be whether—

(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

(I) have not been replaced as of the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, or

(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988, and

(ii) the data are material to the registration.

(D) In the case of a hearing held with respect to action proposed to be taken under paragraph (2), the only matters for resolution shall be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

(E) In the case of a hearing held with respect to action proposed to be taken under paragraph (3), the only matters for resolution shall be whether a registrant willfully submitted material data known to be false.

(F) A decision after completion of a hearing conducted under this paragraph shall be final.

(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.

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[f] *(i)* JUDICIAL REVIEW.—Final orders of the Administrator ıder this section shall be subject to judicial review pursuant to ·ction 16.

:C. 7. REGISTRATION OF ESTABLISHMENTS.

(a) * * *

* * * * * * *

(c) INFORMATION REQUIRED.—

(1) Any producer operating an establishment registered under this section shall [inform the Administrator], *in accordance with regulations promulgated by the Administrator, submit to the Administrator a report* within 30 days after it is registered [of the] *describing* types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which he is currently producing;

(B) which he has produced during the past year; and

(C) which he has sold or distributed during the past year.

The [information] *report* required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform him of the name and address of any recipient of any pesticide produced in any registered establishment which he operates.

(d) CONFIDENTIAL RECORDS AND INFORMATION.—Any information bmitted to the Administrator pursuant to subsection (c) other an the names *and production locations* of the pesticides or active gredients used in producing pesticides produced, sold, or distrib-ed at an establishment shall be considered confidential and shall subject to the provisions of section 10.

'e) PUBLIC RIGHT TO KNOW.—

(1) Any producer operating an establishment registered under this section in any State shall prepare or obtain a fact sheet complying with this subsection for each active ingredient manufactured or used at the establishment. The producer shall maintain copies of the fact sheet at the establishment and shall furnish a copy to any person on request.

(2) Each fact sheet for an ingredient required under paragraph (1) shall—

(A) contain the chemical name, each common name, and any trade name of the ingredient and a summary of relevant health, safety, and environmental data concering the ingredient, and

(B) be revised as often as is necessary to reflect current information about the ingredient.

The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

(3) Each producer to whom this subsection applies shall furıish to the Administrator annually, in accordance with regulaions published by the Administrator, a report that includes—

(A) for each establishment operated by the producer in any State, the name of each ingredient for which a fact sheet is required that is manufactured or used at that establishment, and

(B) for each ingredient for which a fact sheet is required, the location of each establishment where such ingredient is manufactured or used by the producer, and

(C) a current copy of each required fact sheet.

(4) The fact sheets required by paragraph (1) and the annual reports required by paragraph (3) shall be available to the public.

(f) INFORMATION REQUESTED.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall catalogue and retrieve data in such manner as to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data.

[SEC. 8. BOOKS AND RECORDS.

[(a) REQUIREMENTS.—The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

[(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable time to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such

inspection shall be commenced and completed with reasonable promptness.]

SEC. 8. RECORDS.

(a) AUTHORITY TO REQUIRE RECORDS.—The Administrator, by regulation, may require and producer or exporter of perticides, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, or commercial applicator, or any person who distributes or sells any pesticide—

(1) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act,

(2) to furnish to the Administrator reports stating the location where the records are maintained, and

(3) to furnish a copy of any such record to the Administrator on written request.

Except as provided in subsections (c)(d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain, or furnish any record under this subsection with respect to such pesticide.

(b) LIMITATIONS.—The Administrator may not, under the authority of subsection (a), require any person to maintain records of—

(1) financial data, sales data, or pricing data,

(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure, or

(3) research or test data (other than data relating to registered pesticides, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).

(c) RECORDS OF APPLICATORS.—

(1) COMMERCIAL APPLICATORS.—The Administrator shall require each commercial applicator to maintain records of each pesticide application, including the identity and amount of pesticide applied and the date and location of such application, for a period of 2 years after each such application.

(2) PRIVATE APPLICATORS.—No regulations issued by the Administrator to carry out this Act may require any private applicator to maintain any records or file any reports or other documents.

(d) RECORDS OF PESTICIDE DEALERS.—The Administrator, by regulation, shall require each pesticide dealer to maintain a record of each sale or distribution of—

(1) a pesticide classified for restricted use, and

(2) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer shall main-

tain the records required under this subsection for 3 years after the date of the distribution or sale.

(e) ACCESS.—

(1)(A) Any pesticide dealer or commercial applicator shall afford to any employee or former employee of such dealer or applicator access to records required to be kept under subsections (c) and (d) that directly relate to the employee's employment duties.

(B) Any pesticide dealer or commercial applicator shall afford to any customer of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by such an applicator at the request of the customer or under a contract with a customer.

(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph, except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours after the request is made.

(2) A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 upon request by such State agency to the commercial applicator or dealer required to maintain such records.

(f) INFORMATION FOR EMPLOYEES.—An employer who uses or supervises the use of a pesticide shall know or have access to the brand name and common or chemical name of the pesticide and to the safety, first aid, and antidote information listed on the labeling of the pesticide and shall be responsible for promptly making such information available, on request, to any employee exposed to a pesticide and to treating medical personnel.

SEC. 9 INSPECTION OF ESTABLISHMENTS, ETC.

[(a) IN GENERAL.—For purposes of enforcing the provisions of this Act, officers or employees duly designated by the Administrator are authorized to enter at reasonable times, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices.

[Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written state-

ment as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.]

(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—Officers or employees of the United States or of any State, duly designated by the Administrator, are authorized at reasonable times, as provided by this section—

(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, in order to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

(2) to enter any place where there are located any records required under this Act or any place reported under section 8(a) as a location where such records are maintained, to inspect and obtain copies of such records;

(3) to enter any pesticide testing facility, to inspect the facility and the testing being conducted at the facility and to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

(4) to enter any place where such officer or employee has reason to believe that the Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, to inspect such place to obtain evidence of such violation.

[(b) WARRANTS.—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

[(1) entry for the purpose of this section;

[(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or divice found in the establishment which is adulterated, misbranched, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to delivery, movement, or holding of the pesticide or device; and

[(3) the seizure of any pesticide or device which is in violation of this Act.]

(b) WARRANTS.—Officers or employees of the United States or of any State, duly designated by the Administrator, are empowered to obtain and execute warrants authorizing—

(1) entry for the purposes of this section,

(2) inspection and copying of all records required under this Act, and

(3) seizure of any pesticide or device that is in violation of this Act.

* * * * * * *

(d) PROCEDURE.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the inspection and whether a violation of this Act is suspected. Each entry or inspection shall be commenced and completed with reasonable promptness. If the person conducting the entry or inspection obtains any samples of pesticides or devices, before leaving the premises such person shall give to the person in charge of the premises a receipt describing the samples and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished or request to the person in charge of the premises.

(e) COORDINATION.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication or inspections.

SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) * * *

* * * * * * *

(d) LIMITATIONS.—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public[: *Provided,* That the]. *The* use of such data for any registration purpose shall be governed by section 3 of this Act[: *Provided further,* That this]. *This* paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

* * * * * * *

(3) [If] *Except with respect to disclosure of information on inert ingredients in ingredient statements in accordance with section 2(n), if* the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice[: *Provided,* That where]. *Where* the Administrator finds that disclosure of information described in clause (A), (B) or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

* * * * * * *

(h) DATA DISCLOSURE TO STATES.—

(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

(A) the disclosure or use of data or information provided by the Administrator under paragraph (1) to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property, and

(B) the act of a State with respect to such data or information shall be considered an act of the United States.

(3) REQUIRED DISCLOSURE.—The Administrator shall disclose to a State any data or information acquired under this Act if

the State assures the Administrator, and the Administrator determines, that—

(A) the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section, and

(B) the law of the State allows the submitter of the data or information to recover just compensation in a civil action against the State for losses resulting from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or this section.

[SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

[(a) IN GENERAL.—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

[(b) SEPARATE STANDARDS.—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.]

SEC. 12. UNLAWFUL ACTS.

(a) IN GENERAL.—

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to [distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—] *distribute or sell to any person—*

[(A) any pesticide which is not registered under section 3, except as provided by section 6(a)(1);]

(A) any pesticide product which is not registered under section 3 or whose registration has been cancelled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;

* * * * * * *

(2) It shall be unlawful for any person—

(A) * * *

[(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 9;]

(B) to refuse to (i) prepare, maintain, or submit any records required by or under this Act, (ii) submit any reports required by or under this Act, or (iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;

* * * * * * *

(F) *to distribute or sell, or* to make available for use, or to use, any registered pesticide classified for restricted use

for some or all purposes other than in accordance with section 3(d) and any regulations thereunder[: *Provided,* That it]. *It* shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

[(J) to violate any suspension order issued under section 6;]

(J) to violate any suspension order issued under section 3(c)(2)(B), 3A, or 6;

[(K) to violate any cancellation or registration of a pesticide under section 6, except as provided by section 6(a)(1);]

(K) to violate any cancellation order issued under this Act;

* * * * * * *

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to [section 8,] *this Act,* any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

* * * * * * *

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; [or]

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test[.];

(Q) to obtain and use records acquired under section 8(e) in furtherance of a commercial purpose;

(R) to willfully falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

(S) to willfully submit to the Administrator data known to be false in support of a registration;

(T) to violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25(f) of this Act.

* * * * * * *

(c) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by

any person shall be deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEC. 13. STOP SALE, USE, REMOVAL, AND SEIZURE.

(a) * * *

(b) SEIZURE.—Any pesticide or device that is being transported, or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 3;

(C) its labeling fails to bear the information required by this Act;

(D) it is not colored or discolored and such coloring or discoloring is required under this Act; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold: [*Provided,* That upon]. *Upon* payment of the costs of the condemnation proceedings and the executive and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

* * * * * * *

SEC. 14. PENALTIES.

(a) CIVIL PENALTIES.—

[(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.]

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, producer or pesticide testing facility that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If a registrant, applicant for a registration, producer or pesticide testing facility violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $50,000 for such subsequent violation.

(B) Any—

(i) commercial applicator of restricted use pesticides, or

(ii) any other person not described in subparagraph (A) who distributes or sells pesticides or devices,

that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $20,000 for such subsequent violation.

[(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense: *Provided,* That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.]

(2) PRIVATE APPLICATOR.—Any private applicator who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, and any other person not included in paragraph (1) that violates any provision of this Act, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $2,000 for such subsequent violation. The Administrator may waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment.

(3) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity

for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged. *If the person neither resides nor has its principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties.*

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, *the economic benefit (if any) resulting from the violation,* and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

* * * * * * *

(6) SUBPOENAS.—The Administrator, in connection with administrative proceedings under this subsection, may issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and may request the Attorney General to bring an action to enforce any subpoena issued under this paragraph. The district courts of the United States shall have jurisdiction to enforce such subpoenas and impose sanctions.

(b) CRIMINAL PENALTIES.—

[(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.]

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that knowingly violates any provision of this Act shall be fined not more than $50,000 or imprisoned for not more than one year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, that knowingly violates any provision of this Act shall be fined not more than $25,000 or imprisoned for not more than one year, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragarph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than [$1,000,] *$2,000,* or imprisoned for not more than [30] *60* days, or both.

[(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $10,000, or imprisoned for not more than three years or both.]

(3) DISCLOSURE OF INFORMATION.—

(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 shall be fined not more than $25,000, or imprisoned for not more than 3 years, or both.

(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

(i) is granted access to data under section 3(c)(9), and

(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

(I) knowingly violates such section, or

(II) knowlingly allows data to be made available in violation of such section,

shall be fined not more than $100,000, or imprisoned for not more than 3 years, or both.

[(4) ACTS OF OFFICERS AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.]

SEC. 15. INDEMNITIES.

(a) REQUIREMENT.—If—

(1) the Administrator notifies a registrant that he has suspended the registration of a pesticide because such action is necessary to prevent an imminent hazard;

(2) the registration of the pesticide is canceled as a result of a final determination that the use of such pesticide will create an imminent hazard; and

(3) any person who owned any quantity of such pesticide immediately before the notice to the registrant under paragraph (1) suffered losses by reason of suspension or cancellation of the registration,

the Administrator shall make an indemnity payment to such person, unless the Administrator finds that such person [(i)] had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration, and [(ii)] continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator.

* * * * * * *

(c) REPORT.—If the Administrator takes an action that under subsection (a) requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate—

(1) the action taken requires the payment of indemnification,

(2) the reasons for taking such action,

(3) The estimated cost of the payment,

(4) the effect such payment would have on the budget of the Administrator to implement this Act without a specific additional appropriation for the payment, and

(5) a request for the appropriation of funds for such payment.

SEC. 16. ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.

[(a) DISTRICT COURT REVIEW.—Except as is otherwise provided in this Act, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.]

(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to agency discretion by law are judicially reviewable by the district courts of the United States.

* * * * * * *

(e) REVIEW OF REGULATIONS.—

(1)(A) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the regulation by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia circuit. Any petition under this paragraph for review of a regulation shall be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register.

(B) Any refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the Disctrict of Columbia circuit. Any such petition for review of a refusal to modify or rescind a regulation shall be filed within 120 days after such refusal.

(C) The scope of review under subparagraph (A) or (B) shall be as specified in section 706 of title 5, United States Code. The commencement of a proceeding under subparagraph (A) or (B) unless specifically ordered by the court to the contrary, shall not operate as a stay of the regulation.

(2) A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall not be subject to judicial review—

(A) in any suspension, cancellation, or denial proceeding under this Act or in any appeal therefrom, or

(B) in any proceeding under section 13 or 14(a) or subsection (c) or in any appeal therefrom except on request of a person who, as an agricultural producer, is adversely affected by such action.

(3) If a person who is a party to a proceeding described in subparagraph (A) or (B) of paragraph (2) that is based on a regulation issued under this Act petitions the Administrator to modify or rescind such regulation the application of such regulation in the proceeding shall be stayed until the Administrator issues a final decision on the petition.

(4) As used in this subsection, the term 'agricultural producer' means a nongovernmental producer of agricultural commodities who (A) uses or supervises the use of any pesticide for the production of such commodities on property owned or rented by the producer or the producer's employer, or (B) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on such producer's land.

SEC. 17. IMPORTS AND EXPORTS.

[(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwithstanding any other provision this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

[(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D), 7, and 8 of this Act; and

[(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.]

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device, or active ingredient used in producing a pesticide, intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to section 2(p), subparagraphs (A), (C), (D), (E), (G), (H), and (I) of section 2(q)(1), subparagraphs (A), (B),. (C)(i), (C)(iii), and (D) of section 2(q)(2), sections 7 and 8, and paragraphs (2), (3), and (4) of this subsection.

(2) RESTRICTED USE OR UNREGISTERED PESTICIDES.—

(A) This paragraph applies to a pesticide, device, or active ingredient—

(i) for which a restricted use classification has become effective under section 3,

(ii) for which a cancellation or suspension has become effective under section 6,

(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal is associated with concern over potential adverse public health or environmental effects, or

(iv) that is not registered under section 3 for any use.

(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless, at least 30 days before the first shipment each year of such pesticides, devices, or active ingredients to such country, such person has—

(i) notified, under paragraph (3), the person importing the pesticide, devices, or active ingredient and the appropriate government regulatory office in the importing country,

(ii) received written evidence that the notification was delivered to the appropriate government regulatory office, and

(iii) submitted a copy of the notification (in English) and evidence of delivery to the Administrator.

(C) Documents referred to in subparagraph (B) shall be made available to the public, on request.

(3) NOTIFICATION SPECIFICATIONS.—The notification required under paragraph (2) shall be made in an appropriate language and shall contain the following information—

(A) the name of the pesticide and the common and chemical names of each active ingredient,

(B) the name and address of the person exporting the pesticide, device, or active ingredient,

(C) the name and address of the person importing the pesticide, device, or active ingredient,

(D) the name and address of the appropriate government regulatory office in the importing country,

(E) a statement of the reasons why registration of the pesticide was cancelled, suspended, voluntarily withdrawn or the pesticide is not registered in the United States or is classified for restricted use, and the list of restrictions, and

(F) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

(4) LABELS.—

(A) The label of a pesticide intended for export from the United States shall be written in an appropriate language.

(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.

(5) The Administrator, by regulation, may require any person subject to this subsection to prepare, maintain, and submit records as may be necessary to carry out this subsection.

[(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.—Whenever a registration, or a cancellation or suspension

of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.]

(b) NOTICES OF REGULATORY ACTION FURNISHED TO FOREIGN GOVERNMENTS.—

(1) ISSUANCE.—Whenever—

(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective, or ceases to be effective, or

(B) a pesticide is classified for restricted use,

the Administrator shall promptly transmit through the Secretary of State a notice, at such time and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies.

(2) CONTENTS.—A notice under paragraph (1) shall include—

(A) the reasons for the regulatory action taken,

(B) for canceled or suspended registrations, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide, and

(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.

(c) IMPORTATION OF PESTICIDES AND DEVICES.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe[: *Provided,* That the] . *The* Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond[: *And provided further,* That all] . *All* charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and

in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

[(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.]

(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

(1) in cooperation with the Secretary of State, other appropriate Federal agencies, and non-governmental and international organizations, actively participate in international efforts to develop improved pesticide research and regulatory programs,

(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs,

(3) within 1 year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, and every 3 years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to ascertain what procedures are in place in each country—

(A) regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides, and

(B) to control residues on foods to meet tolerances established under United States law, and

(4) report to Congress annually on the activities conducted under this subsection and the results thereof.

SEC. 18. EXEMPTION OF FEDERAL AND STATE AGENCIES.

The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

SEC. 19. [136q] DISPOSAL AND TRANSPORTATION.

(a) PROCEDURES.—Administrator shall, after consultation with other interested Federal agencies, establish procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is [canceled under section 6(c)] *suspended under section 6(c) and canceled* if requested by the owner of the pesticides.

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SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

(a) *SECRETARY OF AGRICULTURE.*—

(a) *SECRETARY OF AGRICULTURE.*—The Administrator, before publishing regulations under this Act, shall solicit the views of the Sec-

retary of Agriculture in accordance with the procedure described in section 25(a).

(b) *VIEWS.*— In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his descretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

(c) *NOTICE.*— In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

SEC. 22. DELEGATION AND COOPERATION.

(a) * * *

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(c) EFFECT ON CERTAIN OTHER LAWS.—The Administrator, in exercising any authority under this Act, shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that such exercise of authority by the Administrator under this Act is not to be considered an exercise of statutory authority for purposes of such section 4(b)(1). To ensure the safety and health of workers, the Administrator and the Secretary of Labor shall seek to reach such agreements and to coordinate the exercise of their statutory authority.

SEC. 23. STATE COOPERATION, AID, AND TRAINING.

[(a) COOPERATIVE AGREEMENTS.—The Administrator may enter into cooperative agreements with States and Indian tribes—

[(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and

[(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.]

(a) COOPERATIVE AGREEMENTS.—The Administrator may enter into cooperative agreements with States and Indian Tribes for the following:

(1) To delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian Tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants.

(2) To provide an amount equal to 50 percent of the anticipated costs of each State or Indian tribe, as agreed under such cooperative agreements, of conducting training programs for certification of applicators. Funds shall be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator.

(3) To provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under such cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State plan of each State approved under section 4(a)(2). Funds shall be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under this subsection.

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SEC. 24. AUTHORITY OF STATES.

(a) *STATE REGULATION.*—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

(b) *UNIFORMITY.*—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

(c) *ADDITIONAL USES.*—(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State[.] *, and such registration shall expire and be of no further effect, without further action by the Administrator—*

(A) at the end of the period, if any, provided as the duration of the registration by the State that approved it, or

(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsec-

tion, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide. *The Administrator shall establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use.*

* * * * * * *

SEC. 25. AUTHORITY OF ADMINISTRATOR.

(a)(1) * * *

* * * * * * *

(3) CONGRESSIONAL COMMITTEES.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, he shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, *Nutrition,* and Forestry of the Senate.

[(4) RULE AND REGULATION REVIEW.—

[(A) CONGRESSIONAL REVIEW.—Notwithstanding any other provision of this Act, simultaneously with promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. Except as provided in subparagraph (B), the rule or regulation shall not become effective, if within 90 calendar days of continuous session of Congress after the date of promulgation, both Houses of Congress adopt a concurrent resolution, the matter after the resolving clause of which is as follows: "That Congress disapproves the rule or regulation promulgated by the Administrator of the Environmental Protection Agency dealing with the matter of , which rule or regulation was transmitted to Congress on ", the blank spaces therein being appropriately filled.

[(B) EFFECTIVE DATE.—If at the end of 60 calendar days of continuous session of Congress after the date of promulgation of a rule or regulation, no committee of either House of Congress has reported or been discharged from further consideration of a concurrent resolution disapproving the rule or regulation, and neither House has adopted such a resolution, the rule or regulation may go into effect immediately. If, within such 60 calendar days, such a committee has reported or been discharged from further consideration of such a resolution, or either House has adopted such a resolution, the rule or regulation may go into effect not sooner than 90 calendar days of continuous session of Congress after its promulgation unless disapproved as provided in subparagraph (A).

[(C) For the purposes of subparagraphs (A) and (B) of this paragraph—

[(i) continuity of session is broken only by an adjournment of Congress sine die; and

[(ii) the days on which either House is not in session because of an adjournment of more than 3 days to a day certain are excluded in the computation of 60 and 90 calendar days of continuous session of Congress.

[(D) EFFECT OF CONGRESSIONAL INACTION.—Congressional inaction on or rejection of a resolution of disapproval shall not be deemed an expression of approval of such rule.

[(E) JUDICIAL REVIEW.—

[(i) Any interested party, including any person who participated in the rulemaking involved, may institute such actions in the appropriate district court of the United States, including actions for declaratory judgment, as may be appropriate to construe the constitutionality of any provision of this paragraph. The district court immediately shall certify all questions of the constitutionality of this paragraph to the United States court of appeals for the circuit involved, which shall hear the matter sitting en banc.

[(ii) Notwithstanding any other provision of law, any decision on a matter certified under clause (i) of this subparagraph shall be reviewable by appeal directly to the Supreme Court of the United States. Such appeal shall be brought not later than 20 days after the decision of the court of appeals.]

(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

* * * * * * *

(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing *or by regulation,* is authorized—

(1) * * *

* * * * * * *

(5) to [prescribe regulations requiring] *with respect to require* any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

* * * * * * *

(d) SCIENTIFIC ADVISORY PANEL.—[The] *Except with respect to a referral under section 3(c)(8)(F)* Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the pre-

scribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall be permanent and consist of *9* members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatifactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS–18 of the General Sechdule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect in receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. [The advisory

panel established under this subsection shall terminate September 30, 1987.] In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

* * * * * * *

(e) PEER REVIEW.—The Administrator shall, by written procedures, for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide[: Provided, That whenever]. *Whenever* the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriation disciplines.

(f) WORKER HEALTH AND SAFETY.—

(1)(A) The Administrator, as soon as practicable, shall promulgate regulations that require the protection, as appropriate and necessary, of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas.

(B) The Administrator shall promulgate regulations that provide for the training, as appropriate and necessary, or employees who mix, load, or apply pesticides. Any training requirement that may be established by the Administrator under this subparagraph shall not apply to any person who is required to receive the training described in subsection (d) or (e) of section 4.

(C) For purposes of subparagraphs (A) and (B), the term "employees" does not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

(2)(A) The Administrator shall promulgate regulations under paragraph (1) for employees not described in subparagraph (B) not later than 3 years after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

(B) The Administrator shall provide a period of at least 6 months for comments on proposed regulations issued under paragraph (1) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas. Such regulations shall be promulgated not later than 2 years after the date of the enactment of the Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1986.

(3) Not later than 6 months after the date of the publication of the notice of proposed rulemaking issued for the regulations for employees described in paragraph (2)(B) to be promulgated under paragraph (1), the Secretary of Agriculture shall submit to the Administrator a report on the impact, cost, and effectiveness of such regulations on the agricultural community. The Secretary shall submit a copy of such report to Congress.

(4) Simultaneously with the promulgation of regulations under paragraph (1), the Administrator shall transmit a copy of such regulations to the Secretary of the Senate and the Clerk of the House of Representatives. Such regulations may not become effective until the expiration of 120 days after the date such regulations are so transmitted.

SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) *IN GENERAL.*—For purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate adequate pesticide use laws and regulations [; *Provided,* That], except that the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

* * * * * * *

(b) *SPECIAL RULES.*—Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 4 of this Act in effect on the date of enactment of the Federal Pesticide Act of 1978 not later than six months after that date.

(c) *ADMINISTRATOR.*—The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. Not withstanding the provisions of section [2(e)(1) of this Act], *2(kk)* during any period when the Administrator has such enforcement responsibility, section [8(b) of this Act] *9* shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section [9(a) of this Act] *9* shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(d) EXPIRATION.—Notwithstanding subsections (a) and (b), the primary enforcement responsibility of a State under this section for pesticide use violation shall expire on January 1, 1989, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14.

SEC. 27. FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.

(a) *REFERRAL.*—Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. [If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.] *If a State—*

(1) does not promptly initiate appropriate investigative action after receiving such referral, or

(2) does not initiate appropriate enforcement action within 90 days after receipt of such referral,

the Administrator may act on such complaint or information in accordance with this Act.

(b) *NOTICE OF INADEQUACY.*—Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) *CONSTRUCTION.*—Neither section 26 of this Act nor this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administra-

tor and the State authority is unwilling or u ıable adequately to respond to the emergency.

* * * * * * *

SEC. 31. COLLECTION, DISSEMINATION, AND USE OF DATA.

(a) DATA SYSTEMS.—The Administrator shall establish, administer, and be responsible for the continuing activities of a committee within the Environmental Protection Agency that shall design, establish, and coordinate an efficient system, within such agency, for the collection, dissemination to other Federal departments and agencies or States, and use of the date submitted to the Administrator under this Act. The Administrator shall ensure the completion, within 36 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, of the design and implementation of the system and procedures required by this subsection. The agency committee so established shall solicit advice from data users outside the Federal Government through means of a permanent advisory committee that shall consist of representatives from private groups, State governments and organizations, and industry, and other representatives as may be appropriate.

(b) DATA RETRIEVAL.—The Administrator, in consultation and cooperation with the Secretary of Agriculture and other heads of appropriate Federal and State departments and agencies, shall design, establish, and coordinate an efficient and effective system for the retrieval of pesticidal, toxicological, and other scientific data that could be useful to the Administrator in carrying out this Act. Systematized retrieval shall be developed for use by all Federal and State departments and agencies with responsibilities in the area of regulation or study of pesticides and their effect on man and the environment.

(c) INDEX.—In designing and implementing the systems required by subsections (a) and (b), the Administrator shall index information by pesticide name, Chemical Abstracts Service registry number, establishment sites, and submitted, so that information can be retrieved in a timely and useful manner.

(d) REPORT.—The Administrator, within 24 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, shall submit a report to Congress on the progress made in designing and implementing the systems for information management required by this section. The report shall address the handling of information submitted before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 as well as the procedures established to ensure that collection information after such date will comply with this section.

(e) CONFIDENTIALITY.—Dissemination of information and data collected under this section to any State shall be subject to section 10.

(f) AUTHORIZATION.—There are authorized to be appropriated for fiscal years 1987, 1988, 1989, 1990 and 1991 such sums as may be necessary to carry out this section.

SEC. 32. GROUNDWATER AUTHORITY.

(a) IN GENERAL.—The Administrator, as appropriate and necessary, shall use the authorities under this Act to provide for the protection of drinking water and groundwater against contamination by pesticides.

(b) USE OF OTHER AUTHORITIES.—In carrying out subsection (a), the Administrator shall use maximum contaminant levels established under title XIV of the Public Health Service Act, whenever available, as groundwater residue guidance levels.

(c) CONSULTATION WITH STATES.—In carrying out subsection (a) the Administrator shall consult with, and take into account the views of, the States on—

(1) the distinction between drinking water. shallow groundwater that is not a potential source of drinking water, and groundwater that is a potential source of drinking water,

(2) degradation of pesticides in groundwater, and

(3) appropriate means for responding to and preventing pesticide contamination of drinking water and groundwater

(d) CONSULTATION WITH SECRETARY OF AGRICULTURE.—In carrying out subsections (a) and (c), the Administrator shall consult with the Secretary of Agriculture.

[SEC. 31. AUTHORIZATION OF APPROPRIATIONS.

[There is authorized to be appropriated to carry out this Act for the period beginning October 1, 1985, and ending September 30, 1986, $68,604,200 of which not more than $11,993,100 shall be available for research under this Act.]

SEC. 33. AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act (other than sections 23(a) and 31) $78,363,500 for fiscal year 1987, of which not more than $13,735,500 shall be available for research under this Act, $87,414,200 for fiscal year 1988, of which not more than $14,343,600 shall be available for research under this Act, $91,673,400 for fiscal year 1989, of which not more than $14,978,200 shall be available for research under this Act, $98,305,800 for fiscal year 1990, of which not more than $15,625,900 shall be available for research under this Act, and $106,808,700 for fiscal year 1991, of which not more than $16,300,100 shall be available for research under this Act.

SECTION 408 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

SEC. 408. (a) * * *

* * * * * * *

(m) [The] *Except as provided in subsection (p), the* Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations estab-

lishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

* * * * * * *

(p) (1) (A) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity—

(i) has been cancelled by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act,

(ii) has voluntarily been cancelled under such Act, or

(iii) has voluntarily been withdrawn under such Act,

due in whol or in part to risks to humans, the administrator, not later than 60 days after the effective date of such cancellation or after receipt of information of such withdrawal, shall revoke any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). In revoking a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used.

(B) The effective date of a revocation under subparagraph (A) may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

(i) the use of the cancelled pesticide before the date of its cancellation,

(ii) the use of existing stocks of such pesticide as authorized under the order cancelling the registration of the pesticide, or

(iii) unavoidable residual environmental contamination.

(2) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act due in whole or in part to risks to humans, the Administrator, not later than 60 days after the effective date of such suspension, shall suspend any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). The effective date of such suspension may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

(A) the use of the suspended pesticide before the date of its suspension,

(B) the use of existing stocks of such pesticide as authorized under the order suspending the registration of the pesticide, or

(C) unavoidable residual environmental contamination.

In suspending a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used. The suspension of a tolerance or an exemption from a tolerance for a pesticide chemical shall be effective as long as the registration of the pesticide to which the tolerance or exemption is applicable is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. If the registration of the pesticide ceases to be suspended and is not cancelled under such Act, the Administrator shall rescind any such suspension of a tolerance or exemption.

(3) At the time the Administrator makes a determination under section 3A(h)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act regarding an ingredient of a pesticide, any tolerance established under subsection (b) for residues of a pesticide chemical that is or contains such ingredient or any exemption from the need for such a tolerance established under subsection (c) shall be reassessed and such tolerance or exemption shall be established amended, or revoked as necessary.

ACT OF AUGUST 4, 1965

AN ACT TO FACILITATE THE WORK OF THE DEPARTMENT OF AGRICULTURE, AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * * * * * *

SEC. 2. (a) * * *

* * * * * * *

(c) The Secretary of Agriculture is authorized to make grants, for periods not to exceed five years in duration—

(1) to land-grant colleges and universities, research foundations established by land-grant colleges and universities, State agricultural experiment stations, and to all colleges and universities having a demonstrable capacity in food and agricultural research, as determined by the Secretary to carry out research to facilitate or expand promising breakthroughs in areas of the food and agricultural sciences of importance to the Nation; and

(2) to State agricultural experiment stations, land-grant colleges and universities, research foundations established by land-grant colleges and universities, colleges and universities receiving funds under the Act of October 10, 1962 (16 U.S.C. 582a et seq.) and accredited schools or colleges of veterinary medicine, to facilitate or expand ongoing State-Federal food and agricultural research programs that (A) promote excellence in research, (B) promote the development of regional research centers, (C) promote the research partnership between the Department of Agriculture and such colleges and universities, such research foundations or State agricultural experiment stations, or (D) facilitate coordination and cooperation of research among States.

The Secretary in making grants under paragraph (2)(B) shall provide support for the interregional project number 4 perogram (commonly referred to as the "IR4 program"). No grant may be made under this subsection for any purpose for which a grant may be made under subsection (d) or for the planning, repairs, rehabilitation, acquisition, or construction of a building or facility. These grants ahll be made without regard to matching funds. Four percent of the amount appropriated for any fiscal year to carry out

this subsection may be retained by the Secretary to pay administrative costs incurred by the Secretary to carry out this subsection.

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